

# Elisys Duo

| User Manual



CE

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**Human**

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Manufacturer:  
HUMAN Gesellschaft für Biochemica und Diagnostica mbH

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# 1 Introduction

Target of this manual is the explanation of the **Elisys Duo** system. After having read the manual, the user should be able to safely operate the **Elisys Duo** system.

## 1.1 Intended Use



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*The **Elisys Duo** system is classified as other IVD.*

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The **Elisys Duo** is designed to automate diagnostic ELISA / EIA and autoimmune assays that are available from Human. The system is to be used in clinics, laboratories, universities and hospitals containing diagnostic facilities as well as blood banks. The workplace for the system shall be a dedicated laboratory (area) for diagnostic purposes. The laboratories are not restricted to, but may include small working spaces (areas). The system is not to be used in a near patient environment.

The **Elisys Duo** consists of a platform that performs ELISA and similar structured assays, and a PC software that performs several system tasks and provides a graphical user interface. The **Elisys Duo** has an interface that can accommodate with an internal PC. The PC has a data connection to an external laboratory information system (which is not included in the **Elisys Duo**).

The **Elisys Duo** has a loading bay for samples and reagents, and a loading bay for disposable tips. The **Elisys Duo** also has cavities for loading microplates. Loading of any of these items into the **Elisys Duo** instrument is to be performed by the operator. Sample and reagent vessels come with attached bar codes that encode the identifier of the corresponding sample or reagent. The **Elisys Duo** reads the bar codes and stores the identifier. Bar codes on microplates can not automatically be scanned by the system.

## 1.2 Typographical Conventions

The symbols described hereafter are used in the current manual, on the instrument and on its packaging. In addition, a specific notation is used to refer to certain particular elements, e.g. buttons, keys.

### 1.2.1 Warning Messages

Warning messages are displayed using a safety symbol and printed in special types. For special situations were used the following security symbols.



***Caution, risk of danger to person or damage to equipment! Consult instructions for use!***



***Biohazard!***



***Electrical hazard!***



***Caution, hot surface!***



***Mechanical hazard!***



***Automatic start-up!***



***Laser hazard!***

## 1.2.2 Notes

Notes are indicated with a symbol and printed in special types. The following symbols are used in particular situations.



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*Consult instructions for use!*

---



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*Notes are indicated by this symbol and printed in special types.*

---



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*Disconnect mains power connector before servicing!*

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*Information about the required access rights for **Elisys Duo** software functions.*

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## 1.2.3 Symbol Keys



Manufactured by



In Vitro Diagnostic



Lot number



Expiration date



Temperature limitations



CE mark



ID number



Serial number



See chapter 1.3.8 on page 1-11

## 1.2.4 Special Types

### LEDs and Signal Lamps

LEDs (light emitting diode) and signal lamps are printed in special type.  
Example: Power LED

### Fields

Fields are printed in bold type.  
Example: **ID** field

### Menu items and Buttons

Menu items and buttons are printed in spaced type.  
Example: **O p e n** button.

### Keys

Keys are printed in slanted type.  
Example: Press *Enter*

### File examples

File examples are printed in typewriter font.  
Example: `DRIVER=C:\SERVICE\DRIVERS`

## 1.2.5 Abbreviations

Abbreviation	Meaning
*.???	Different file extensions (e.g. *.asy, *.txt), see chapter 7.1.6.1 on page 7-9.
APM	Aspirate Pressure Monitoring system
ASCII	American Standard Code for Information Interchange (ASCII), pronounced is a character encoding based on the english alphabet.
ASTM	American Society for Testing and Materials. ASTM 1381 and ASTM 1394 are determinations for the communication between computers.
COM	COM is the original, yet still common, name of the serial port interface on PCs. It might not only refer to physical ports, but also to virtual ports, such as ports created by RS/232 or USB adapters.
COP	Command Operating Processor
CU	Control Unit
CV	The abbreviation CV stands for “coefficient of variation” and is the relative standard deviation, which is the quotient of the absolute standard deviation and the mean of a measured value. %CV: The CV multiplied with 100%
EEPROM	An Electrically Erasable Programmable Read-Only Memory, is a type of non-volatile memory used in computers and other electronic devices to store small amounts of data that must be saved when power is removed, e.g., calibration tables or device configuration.
EIA	Enzyme Immuno Assay
ELISA	Enzyme Linked Immuno Sorbent Assay
Host	In computer networking a host is a main computer (e. g. server, central computer).
ID	Identification (Number).
LAN	A Local Area Network is a computer network.
LED	Light Emitting Diode
LIMS	A Laboratory Information Management System (LIMS) is computer software that is used in laboratories for the management of samples, laboratory users, instruments, standards and other laboratory functions such as invoicing, plate management, and work flow automation.
LIS	A Laboratory Information System, is a class of software which handles receiving, processing and storing information generated by medical laboratory processes.
LLD	Liquid Level Detection

Abbreviation	Meaning
μl	A microliter is a unit of volume in the metric system. (1 μl = 0.001 ml = 1*10 <sup>-6</sup> l)
nm	A nanometer is a unit of length in the metric system. (1 nm = 0.000001 mm = 1*10 <sup>-9</sup> m = 39.37*10 <sup>-9</sup> in)
OD	Optical Density
PC	Personal Computer
PS2	The PS/2 (PS2) connector allows the connection of a keyboard or a mouse to a computer.
QA	Quality control Analysis
RS232	Serial bus standard to connect devices to a computer.
USB	The Universal Serial Bus is a serial bus standard to connect devices to a computer.
VC	Validation Criteria
VGA	The Video Graphics Array is a standard interface to connect a screen to a computer.

*Table 1-1: Abbreviations*



## 1.3 Safety Instructions



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*Read all of these instructions! Retain these instructions for reference!*

---



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*The following safety instructions must be observed at all times, both before and during operation of the **Elisys Duo** system!*

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*The operating manual must be kept near the instrument and must be accessible to the user at all times.*

---

The **Elisys Duo** system is designed and manufactured in accordance with the safety requirements for electronic and medical systems. If the law issues regulations concerning the installation and/or operation of the instrument, then it is the operator's responsibility to adhere to them.

The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The systems are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

### 1.3.1 General Safety



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**Follow all warnings and instructions marked on the instrument and in this manual.**

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**The instrument must only be operated by personnel who have been trained to use the system.**

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It is strongly recommended that all first time personnel read this manual prior to working with the instrument

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**The instrument must only be used in accordance with its intended use.**

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Use only the consumables and accessories described herein (e. g. tubes, disposable tips, microplates, etc.).

The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system.

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**The operator may only perform the maintenance work described in this manual.**

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Use only the parts recommended in this manual for servicing.

The tests and maintenance work defined by the manufacturer should be performed to make sure that the operator remains safe and that the instrument continues to function correctly.

Trained, qualified and authorised service personnel and technicians must perform any service and maintenance work not described in this manual.

Any changes made to the instrument that are not authorised by the manufacturer will lead to the loss of guarantee.

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**The system was developed and tested according to the regulations of the IVD directive.**

Any changes to the instrument that are not authorised by the manufacturer will lead to the loss of the validity of the conformity to the applicable regulations the manufacturer has declared. In this case, the customer is responsible for the fulfilment of the applicable regulations.

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**The instrument may be opened, serviced and repaired by trained, qualified and authorised service personnel only.**

### 1.3.2 Electrical Safety

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**For safe electrical operation of the installed instrument the relevant regulatory provisions have to be observed.**

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**Check that the operating voltage is set correctly on all instrument components before you connect the system to the mains supply.**

This product must be operated from the type of power source indicated on the type label. If you are not sure of the type of power available, consult an authorized sales person or your local electric power company.

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**Use a 3-wire grounding type plug to connect the instrument and all peripherals to mains supply.**

Use only extension cables with a protective conductor and grounded contact.

Grounding of the instrument and its peripheral devices to the same protective earth potential must be ensured.

Never interrupt the grounding contacts.

There is the risk of an electrical shock if the protective conductor is interrupted within or outside the device, or has been disconnected.

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**The instrument must be connected with a delivered connection cable to dedicated socket. The use of a multi plug is not allowed!**

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**Do not allow anything to rest on the power cord.**

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**If you can see that the instrument has become unsafe to use, switch it off and disconnect it from the mains supply.**



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**If liquid gets inside the instrument, switch it off and disconnect it from the mains supply. Clean, and dry the respective parts.**

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**Surfaces (floors, work table) must be dry when you are working with the system.**

Only use the bottles, tubing and components supplied and recommended for containing liquids on the instrument.



**Spare fuses must match the values (nominal voltage, nominal current, and type) specified by the manufacturer.**

Always replace blown fuses, do not try to repair them.

Never short-circuit the fuse holder.



**Switch the instrument off and disconnect it from the mains supply before servicing.**

Only when directed to do so, should power be supplied. If power is supplied while any covers are removed, use extreme caution while servicing the system.

**Never remove protective guards or secured components as this could expose live parts.**

Electrical connection contacts (plugs, sockets etc.) can be electrically live.

Even after the device has been switched off, components (e. g. capacitors) can carry a voltage.

All current-carrying parts are sources of danger for an electrical shock.

**Ensure the instrument is positioned so that the power supply and main switch is easily accessible.**

**The instrument meets the requirements described in standard IEC 61326 on transient emissions and interference resistance.**

This instrument was developed and tested according to CISPR11 Class A. It can cause radio interference in domestic environment. In this case it may be required to take action to eliminate such interference.

Before setup and operation of the instrument, the electromagnetic environment should be evaluated.

Do not use the instrument in the vicinity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) since they could interfere with the proper operation of the instrument.

### 1.3.3 Laser Safety



**Care must be taken when operating and testing the bar code scanners as they use a laser class 2. Never look directly into the laser beam!**

Output causes irritations of the eye if stared into the beam for long periods of time.

See chapter 11.2 on page 11-1 for technical data of the laser (bar code scanner).

For operating and testing the laser, no optical devices may be used.

For operating and testing the laser, watches and mirroring jewellery should be removed.



**Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.**

### 1.3.4 Mechanical Safety

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**Do not place the instrument on an unstable or uneven surface.**

The instrument may fall, causing serious damage to the instrument or injure the user.

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**Never open screw-attached housing parts while the instrument is on.**

There is a risk of injury due to moving parts (fan, motor drives).

Only when directed to do so, should power be supplied. If power is supplied while any covers are removed, use extreme caution while servicing the system.

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**Do not take off the protective cover during a run and do not reach into the working area.**

Improper handling may cause serious damage to the instrument or injure the user.

If you open the flap or cover, verify that the movement of the pipettor has stopped before you reach into the working area.

Avoid touching the pipettor and other moving parts while the system is in operation.

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**Slots and openings are provided for ventilation (are not meant as access points).**

To ensure reliable operation of the instrument and to protect from overheating, these openings must not be blocked or covered.

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**Sharp edges! Sheet metal parts and PCBs located behind protective covers might have sharp edges. Contact might lead to injuries.**

Wear cut resistant gloves!

Use caution at corners and edges!

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### 1.3.5 Biological Safety

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**Risk of infection! Handling of samples and reagents:**

Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument which were in contact with samples/test reagents.

The above-mentioned parts are to be treated as being potentially infectious.

Reagents can lead to irritation of the skin and mucous membranes.

Use appropriate gloves, a lab coat, and eye protection (e.g. goggles)!

Observe the instructions in the package inserts for a correct use of the reagents.

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**If sample material is spilled in the system, clean and disinfect it immediately by the use of a validated method.**

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**For reagent containers and tubing's (system liquid and waste), no guarantee can be provided for any resistance against organic solvents.**

For this reason, do not use any organic solvents unless such solvents are expressly authorised.

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**Do not autoclave the containers for liquids and waste!**

### 1.3.6 Touch Screen Handling and Cleaning

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**Operate with a stylus (tip R0.8 or over), or with a finger without applying excessive load.**

Sharp edged or hard articles are prohibited.

It is absolutely forbidden to draw lines along with the edge of the housing because the extreme force will damage the PET/FILM and cause the failure of the touch panel.

Keep the surface clean.

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**Use soft clothes with neutral detergent or with ethanol may to clean the touch screen.**

Do not use any chemical solvent, acidic or alkali solution.

Do not allow liquid from soaking into the joint of film and glass which may result in peeling or malfunctioning.

### 1.3.7 Cleaning the System



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**Switch the instrument off and disconnect it from the mains supply before cleaning, disinfection or decontamination.**

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**Liquid detergents, disinfectants or decontamination liquids may not be poured into the instrument or sprayed inside the system.**

For the cleaning, disinfection or decontamination, a cloth moistened with detergent, disinfectant or decontamination liquid should be used.

Only approved detergents, disinfectants or decontamination liquids may be used.

Only approved cleaning, disinfection or decontamination methods may be used.

For cleaning, disinfection or decontamination, the regulations of the relevant regulatory provisions must be observed.

### 1.3.8 Disposal



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**Potential infectious material and all parts that may come in contact with potential infectious material must be disposed according to the applicable local and national provisions, legislation and laboratory procedures.**

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**All parts that have been replaced, must be disposed according to the applicable local and national provisions and legislation.**

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**The instrument must be disposed according to the applicable local and national provisions and legislation.**

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**The packaging material must be disposed according to the applicable local and national provisions and legislation.**

## Introduction

### Safety Instructions

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**Single-use containers or tips may not be used repeatedly.**

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**In the European Union, electrical and electronic equipment must not be disposed of with other household-type waste. It must be collected separately. Please observe the relevant legal regulations effective in your country.**

## 1.4 Positions of Safety Labels and Type Label



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***If any label gets lost, replace it by an equivalent label!***

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### 1.4.1 General Warning Labels



General warning labels are positioned on:

- on the pipettor arm,
- on both sides of the loading bay,
- on both edges of the cover, and
- next to the dispense pump

### 1.4.2 Biological Hazard Labels



Biological hazard labels are positioned on:

- the washer service cover,
- the disposable tip ramp,
- the pumps module cover,
- the waste liquid container, and
- both washer aspiration bottles.

### 1.4.3 Electrical Hazard Labels



Electrical hazard labels are positioned on:

- the main power connector/switch.

### 1.4.4 Laser Hazard Labels



Laser hazard labels are positioned on:

- the loading bay bar code scanner.

### 1.4.5 Type Label

The type label is positioned on the right side of the instrument (near by the mains switch).

## Introduction

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Positions of Safety Labels and Type Label



## 2 System Description

The **Elisys Duo** is a fully automated microtiter plate analyser performing the complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation. The instrument is controlled via the Windows PC **Elisys Duo** software. This software, which was specifically designed for this purpose, allows the user to process the pre-defined assays as well as assays programmed by the user. The clear structure with intuitive user-guidance allows simple and quick operation of daily routine jobs as well as programming of user-specific assays.

## 2.1 System Overview

### 2.1.1 System

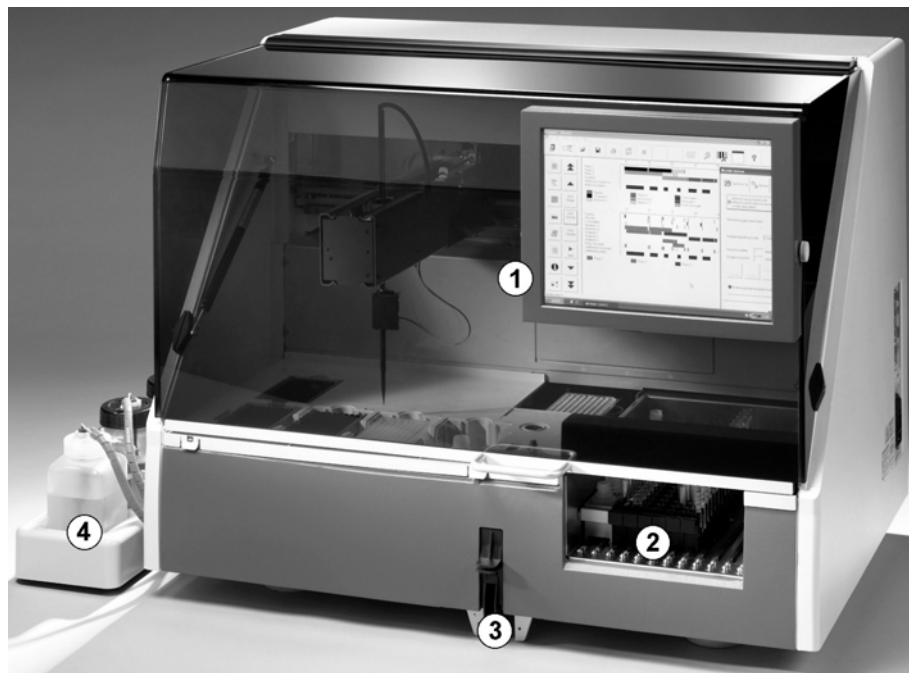


Figure 2-1: **Elisis Duo** system

- |   |   |
|---|---|
| 1 | Cover with touch screen   |
| 2 | Rack system for samples and reagents (see chapter 2.2.4 on page 2-12)                     |
| 3 | Tip ejection station and waste bag for disposable tips (see chapter 2.2.8.4 on page 2-16) |
| 4 | Wash buffer bottles and waste bottles for the washer (see chapter 2.2.5 on page 2-14)     |



*Only open and close the cover with the handle!*

## 2.1.2 Instrument Modules

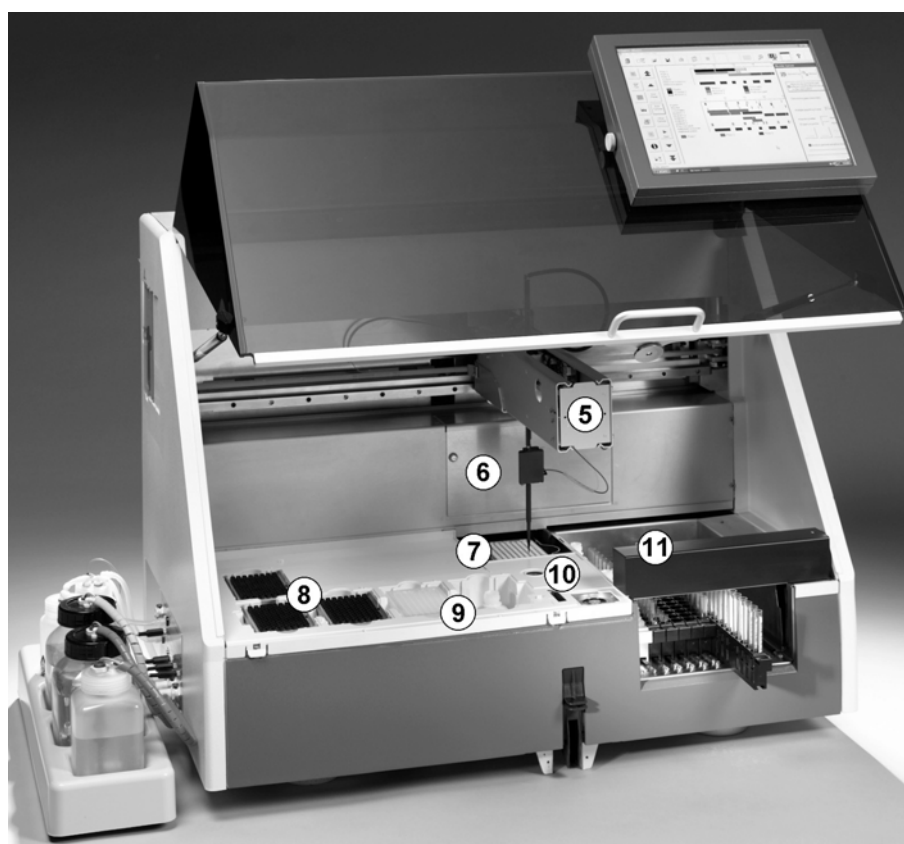


Figure 2-2: **Elisis Duo** system - instrument modules

- |    |   |
|----|---|
| 5  | Pipettor (see chapter 2.2.8 on page 2-15)   |
| 6  | Service cover of washer (see chapter 2.2.5 on page 2-14)  |
| 7  | Plate transport (see chapter 2.2.1 on page 2-7)   |
| 8  | 3 positions for disposable tip racks (see chapter 2.2.2 on page 2-9)                                    |
| 9  | Positions for dilution or archive plates (see chapter 2.2.3 on page 2-10)                               |
| 10 | Pipettor wash station, tip eject station and cover locking mechanism (see chapter 2.2.8.4 on page 2-16) |

## 2.1.3 Liquid Connections



Figure 2-3: Left side - liquid connections

12	Dispense pump (see chapter 2.2.8 on page 2-15)
13	Liquid connections (for details see below)
14	2 washer waste bottles (vacuum extraction) (see chapter 2.2.5 on page 2-14)
15	3 wash buffer bottles (see chapter 2.2.5 on page 2-14)
16	System liquid container (see chapter 2.2.8.2 on page 2-15)
17	Waste liquid container (see chapter 2.2.5 on page 2-14)



***The waste liquid container, the washer waste bottles, and the corresponding tubings could have had contact with infectious material. Pay attention to safety regards! Always wear appropriate gloves, lab coat, and goggles!***



*The waste liquid container should be placed always under the level of the analyser.*



*The installation of washer liquid waste bottle and washer foam bottle must be lined up, that they cannot accidentally fall over during operation!*

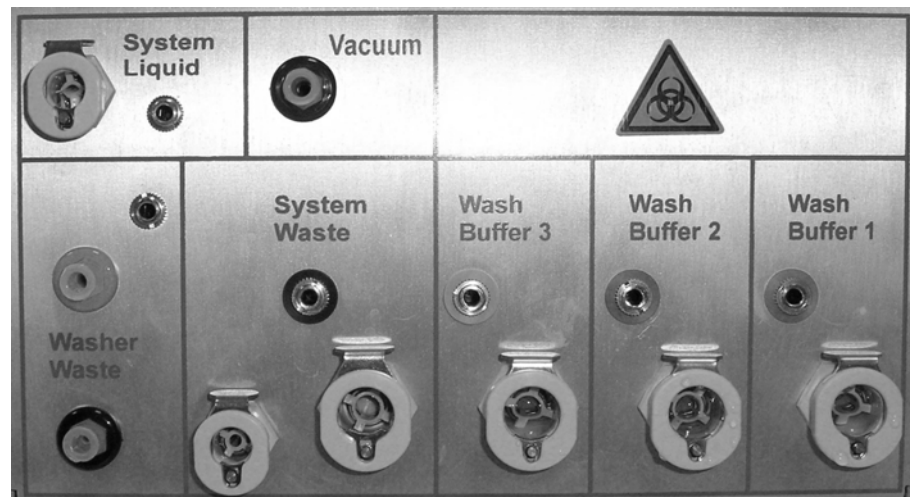


Figure 2-4: Liquid connections

System Liquid	System liquid container
Vacuum	Washer liquid waste bottle (trap bottle)
Washer Waste	Washer foam bottle (vacuum bottle)
System Waste	Waste liquid container
Wash buffer 3	Wash buffer bottle - yellow channel
Wash buffer 2	Wash buffer bottle - blue channel
Wash buffer 1	Wash buffer bottle - red channel

## 2.1.4 Electrical Connections



*Figure 2-5: Right side - electrical connections*

USB	3 USB-connectors
VGA	External monitor connector
PS2	External mouse/keyboard connector
RS232	Serial interface connector (RS 232)
LAN	Network connector (LAN)
18	Main power connector with power switch and main fuses

## 2.2 Use of the Modules

### 2.2.1 Microplates in the Plate Transport

The plate transport moves microplates between the modules of the **Elisys Duo** system.

The plate transport can also shake a microplate in order to mix the well contents. The microplate is moved linearly at a given frequency and amplitude. The shaking time is controlled through the assay protocol.



*You may only insert the microplates into the plate transport if you are requested to do so by the **Elisys Duo** software!*



*Use only exact modelling of microplates to ensure correct tracking.*

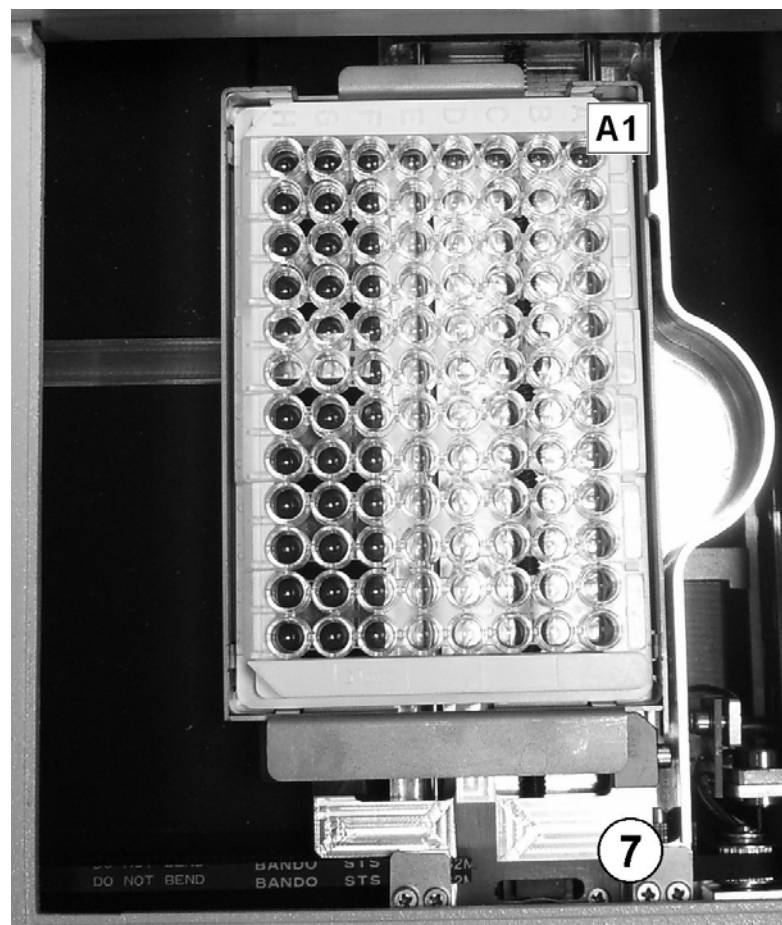


Figure 2-6: Microplate in the plate transport

## System Description

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### Use of the Modules

Load the microplate into the plate frame of the plate transport (7) after the request of the **Elisys Duo** software. Position A1 should be at the rear right. Push the microplate firmly down so that they lay on the floor completely and evenly.



## 2.2.2 Disposable Tip Racks

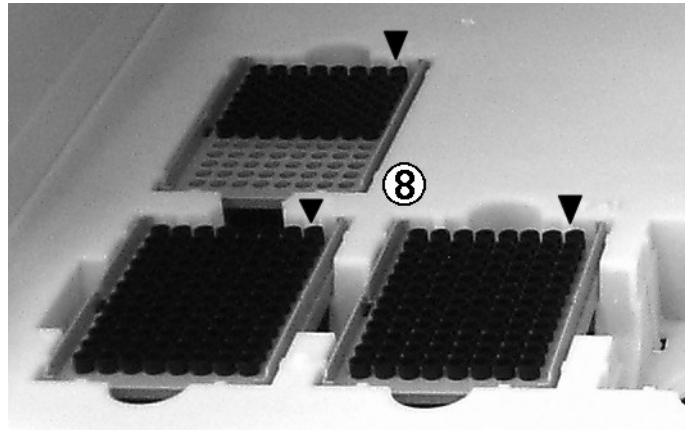


Figure 2-7: Disposable tip racks



*Please carefully check the tip racks allocation, following the specific color code and type in the software. A tip misplaced can not be recognized by the instrument and may cause mechanical damage!*

Insert the disposable tip racks into the corresponding rack position (8) after the request of the **Elisys Duo** software. The rack marker should be at the rear right (see triangular markers). Push the disposable tip rack(s) firmly down so that they lay on the floor completely and evenly.

### 2.2.3 Dilution or Archive Plates



*To be able to use dilution or archive plates, it is required to use a metal base plate. The metal base plate allows the correct detection of liquid surface as well as the usage of the complete liquid volume in the dilution or archive plate (less the specified remaining volume).*



*Use only exact modelling of microplates to ensure correct tracking.*

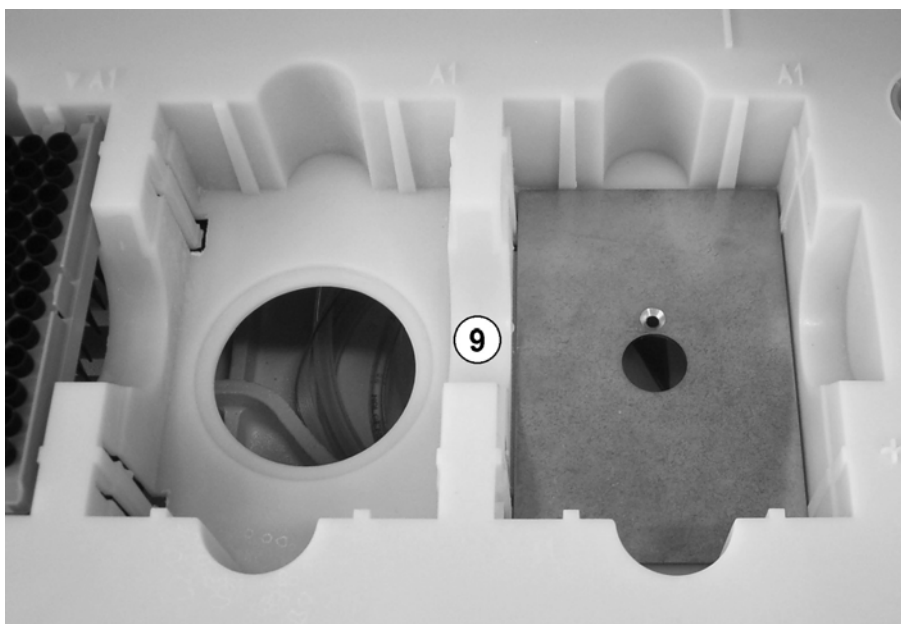
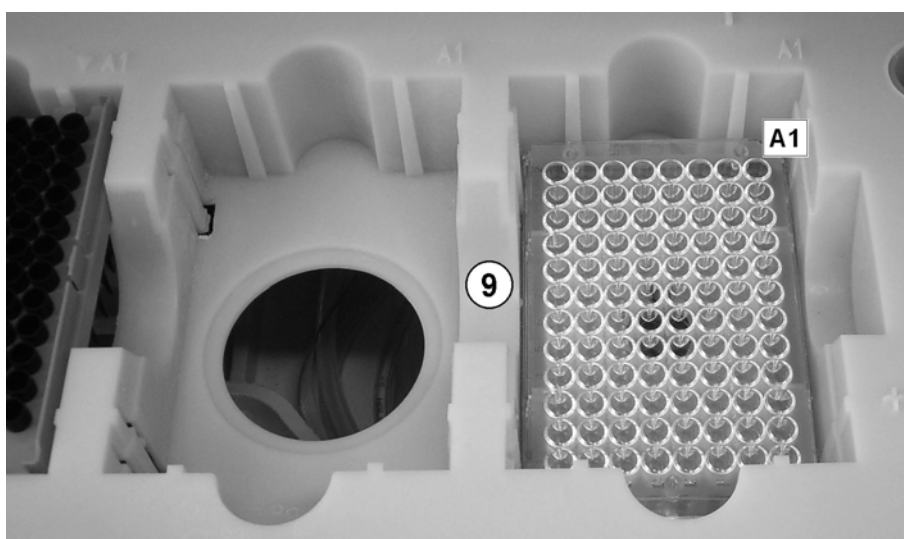


Figure 2-8: Metal base plate in the right position

Lay the metal base plate on the corresponding position (9) after the request of the **Elisys Duo** software. Push the metal base plate firmly down so that they lay on the floor completely and evenly.



*Figure 2-9: Dilution or archive plate in the right position*

Lay the dilution or archive plate on the metal base plate. Position A1 should be at the rear right. Push the dilution or archive plate firmly down so that they lay on the floor completely and evenly.

## 2.2.4 Rack System for Samples and Reagents

The rack system is used for loading samples and reagents located in reagent tubes or bottles into the **Elisys Duo** system by means of so-called racks. By means of the pipettor, the samples and the reagents can then be distributed in the course of a test run.

To avoid the confusion of samples or reagents, the rack system is provided with a bar code scanner (on the right hand side). By means of this scanner, the bar codes, which are applied on the corresponding reagent tubes or bottles can be read and processed in the **Elisys Duo** software later.



---

**CAUTION: Laser radiation - do not stare into beam!**

---

The rack system is provided with 12 tracks for insertion of up to 12 racks, depending on their width. The track to be used is marked by lamp (LED).



---

***Never move your hand into the rack system, if the Elisys Duo system is operating. The pipettor could cause injury during the loading of samples or reagents with its tip.***

---



---

*Do always push in the racks into the rack system with the handle or pull it out again with the handle.*

---



---

*Insert the racks carefully to avoid tipping over and spilling of bottles or tubes.*

---



---

*In one rack, only tubes of the same type may be used to avoid problems during the aspiration of liquids. The tube type must be approved for the relevant rack.*

---



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*Never load more than one rack at the same time! For proper bar code identification the racks must be loaded one after the other, as indicated by the LEDs.*

---

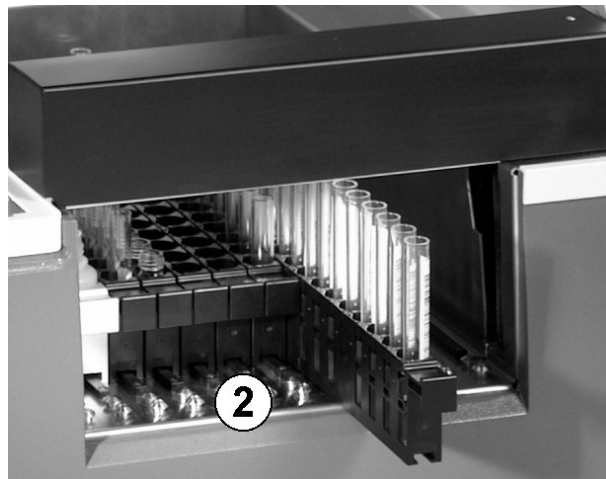


Figure 2-10: Rack system with racks

#### 2.2.4.1 Racks

Racks are used for loading samples and reagents located in reagent tubes or bottles into the rack system in a controlled way. Depending on the purpose of use, there are different racks.



*In one rack, only tubes of the same type may be used to avoid problems during the aspiration of liquids. The tube type must be approved for the relevant rack.*



*Use only exact modelling of tubes and bottles to ensure correct tracking.*

Each rack includes a contact pin; on racks occupying one track, this pin is located at the top centre, and on the broader racks at the top right.

The software specifies which track is to be used for the respective rack. This is indicated by a LED. A reagent rack occupying 3 tracks must be inserted such that the contact tappet is in contact with the lit up LED. Each rack has to be inserted up to the limit stop.

Reloading of sample and reagent racks is possible when the instrument is in the incubation mode.

The following racks are supplied:

- T:** Sample rack for 16 patient samples (occupies one track).
- 4:** Calibrator and control rack for 15 bottles (occupies one track).
- 5:** Combi rack for 6 round bottles and 2 square bottles for reagents (occupies two tracks).

## **2.2.5 Washer and Wash Buffers**

To be able to wash microplates in the course of a test, the *Elisys Duo* system is provided with a washer. By means of the washer, the microplates can be cleaned strip-wise with different wash buffers.

The wash head of the washer aspirates liquid from the microplate wells as well as dispenses wash buffer into them. The wash head comprises eight-dispense nozzles and eight slightly longer aspiration nozzles. The wash head is lowered into the microplate wells for each aspiration or dispensing step.

The washer is located behind a cover (6).

A maximum of 3 bottles (1 x 1 litre, 2 x 2 litres - 15) can be used for various wash buffers to clean the microplates and cleaning fluid (e.g. distilled water) to clean the washer head.

The connection fitting (13) consists of 3 colour-coded connection pairs: one tubing and one level sensor each per bottle.

Two waste bottles (14) are available for the wash unit. One waste bottle contains the liquid waste which is pumped to the waste container which is positioned below the instrument. The second bottle serves as overflow protection.

## **2.2.6 Incubator and Stacker**

Next to the washer there are two independent heatable incubator chambers; the microplates are automatically transported into these incubators and out again according to the assay protocol.

The heatable incubator chambers can also shake a microplate in order to mix the well contents. The microplate is moved linearly at a given frequency and amplitude. The shaking time is controlled through the assay protocol.

The instrument is also equipped with three light-protected storage chambers (stacker) accommodating microplates for room temperature incubation. It is located below the incubator.

## **2.2.7 Photometer**

The photometer uses photodiodes located above the microplate to measure the amount of light passing through the microplate wells from the light source below the microplate. The optical system includes optical interference filters (up to 8 filters), mounted in a filter wheel, to obtain monochromatic light of the desired wavelength and optical lenses to obtain an optimal light beam passing through the microplate wells.

The photometer measures the absorbance in eight wells simultaneously as the microplate moves through the photometer. Comparing the measurement values to the zero value with air in between (equivalent to 100 % light source output), the absorbance is calculated using the Lambert-Beer law. A reference channel continuously compensates for any instability of the light source.

The photometer (400 - 700 nm) is installed in the lower left part of the instrument.

## 2.2.8 Pipettor and Dispense Pump

The **Elisys Duo** system is provided with a fully automatic pipetting system.

The microprocessor-controlled dispense pump (12) installed on the left side of the system allows a very precise aspiration and dispensing of the liquids to be pipetted. The tube system of the pipetting system is filled with system liquid.

The pipettor uses disposable tips to avoid cross-contamination. Different sizes of disposable tips (300 µl or 1100 µl) can be attached to the tip adapter of the pipettor automatically. After pipetting the disposable tips can be emptied in the wash station (10) or dropped into the tip eject station (10).



---

***A plastic cover protects the visible working area. The closed position of this flap is monitored by a contact switch. The Elisys Duo cannot be operated without this cover, in order to protect the operator from getting in contact with the working area during a run. If these safety precautions are not observed strictly, the operator may get hurt or contract an infection, or the instrument may get damaged.***

---



---

*In case no cover lock is installed, the software can be configured so that the system is stopped immediately when the instrument cover is opened during a run.*

---

### 2.2.8.1 Dispense Pump

The dispense pump is used for transferring liquids (samples, controls, standards, reagents or diluents).

The disposable tip is moved into the source position (e.g. sample, reagent) by the pipettor to aspirate liquid. The downward motion of the pump's syringe plunger causes the system liquid to aspirate fluid into the disposable tip.

After the liquid is aspirated, the tip is moved to the destination position (e.g. microplate, dilution plate). The upward motion of the syringe plunger causes the system liquid to dispense fluid through the disposable tip into the destination position.

The motion of the syringe plunger coupled with the system liquid causes system fluid to move throughout the tubing and the aspiration and dispensing of liquid and airgaps in the disposable tip.

### 2.2.8.2 System Liquid Container

The system liquid container (16) is located beside, behind or under the instrument and connected through tubing. The system liquid container is fitted with an electric level sensor.

The system liquid can be filled as soon as the instrument is properly installed.

To fill system liquid:

1. Prepare the system liquid (deionised water).
2. Open the container screw cap and pour in the system liquid.
3. Close the screw cap and make sure the level sensor and connections are correctly set.

The level sensor is used by the system to check the available quantity of system liquid. This check is performed each time a selftest is conducted (see chapter 5.1 on page 5-1). The system will also warn the operator if the level of system liquid becomes insufficient during a run.

A visual check of the system liquid container is recommended every morning before starting the system (see chapter 8.2 on page 8-3).

#### 2.2.8.3 Liquid Level Detection (LLD)

Each disposable tip possesses independent liquid level detection (LLD) capabilities. LLD detects liquid by detecting a change in capacitance. As a tip enters the sample or reagent well (source or destination) the LLD circuitry baselines. The tip continues to track down until a change of capacitance is detected. Once liquid is detected, the tips submerge in the liquid to a programmed submerge depth. As the system aspirates/dispenses liquid the tip tracks down/up while liquid level decreases/increases. Tracking is done by calculating the change of liquid level using the well geometry. This mechanism ensures that sample or reagent will be aspirated/dispensed without unnecessary external contamination of the tip.

Disposable tips with LLD capability are impregnated with carbon and are black in color. These are denoted as “conductive” tips. Tips not impregnated with carbon, normally clear in color, have no LLD capability and can only be used if a fixed height for aspirating or dispensing is used.

#### 2.2.8.4 Tip Ejection Station and Pipettor Wash Station

##### **Tip ejection station and waste bag (10):**

The opening serves as ejection station for disposable tips. The ejected tip is transported into the waste bag via a slide which is attached to the front side of the instrument. The waste bag can be taken out of the holding device and replaced. After removal of the waste bag, the ejection station can be pulled off by hand.



---

---

***The ejection station and the waste bag could have had contact with infectious material. Pay attention to safety regards! Always wear appropriate gloves, lab coat, and goggles!***

---

---

##### **Pipettor wash station (10):**

The pipettor wash station is located behind the tip ejection station.



## 2.2.9 Touch Screen

With the integrated touch screen it is very easy to use the system. You made all inputs with a stylus (tip R0.8 or over) or a finger directly on the touch screen. An external keyboard or mouse are not needed.

Use:

- Keyboard (alphanumeric inputs, e.g. A - Z, 0 - 9, etc.):  
The **Elisys Duo** software provides special input dialogs to enter letters (see chapter 3.6.1 on page 3-21) or numbers (see chapter 3.6.2 on page 3-23). Additional there is a callable screen keyboard to enter letters or numbers on the windows systems (see Windows Start button).
- Mouse:  
Mouse pointer: Touch the screen with your finger. Now the mouse pointer will follow your moving finger.
- Single mouse click: Touch the screen with your finger once.
- Double mouse click (double click): Touch the screen with your finger twice. Do not wait between the first and the second touch.



---

*Note the handling and cleaning hints for touch screens in the safety instructions (see chapter 1.3.6 on page 1-11).*

---

## 2.3 Accessories and Consumables

The necessary accessories and the following consumables can be purchased from Human:

- Sample and reagent racks (with bar codes).
- Bar code labels for reagent and sample racks.
- Tip racks with 300 µl / 1100 µl disposable tips.
- Waste and system liquid containers with or without level sensors and tubing connections.
- Wash buffer and clean fluid bottles.
- Trap flask and vacuum flask.
- Spare reagent bottles.
- Bar code labels for reagent bottles.
- Various tubings.
- Filters for the photometer.
- Halogen lamp for the photometer.
- Sample rack storage tray.

## 2.4 Principles of Methods

### 2.4.1 Absorbance Photometry

The measurement principle of absorbance photometry plays the most important role in clinical chemistry. With this method, the intensity of a monochromatic light beam of a suitable wavelength is compared before and after passing through a sample. The degree of attenuation of intensity of the light beam provides a measure of the concentration of the substance under investigation. The photometer consists of a polychromatic or monochromatic light source. In the case of the **Elisys Duo**, this is a halogen lamp which emits a spectrum. The desired wavelength is filtered out using a wavelength selector (i. e. a filter). The light with this wavelength passes through the sample with the substance to be measured in an optically clear solution. A part of the light is absorbed in the sample. The intensity of the light coming out of the sample is measured with a measuring cell (detector). The light striking the detector is converted into an electrical signal and stored as the measurement signal.

### 2.4.2 Bichromatic Measurement

In the case of the bichromatic measurement principle, measurements are performed at two wavelengths, the measuring and the reference wavelength. The measuring wavelength is close to the absorbance maximum of the chromogen. The absorbance is mainly dependent on the amount of chromogenic substance in the sample. The reference wavelength lies outside the absorbance range of the chromogen and indicates the blank value of the sample. The absorbance value of the reference wavelength is subtracted from the absorbance value of the measuring wavelength. In this manner, external influences such as scratches on the microtiter plate, dust, turbidity of the solution and the drift of the electronic measuring instrument can be compensated.



## 3 Basic Functions

This chapter describes the basic functions of the **Elisys Duo** software. Additionally, a short overview over all software menus and symbols is included in this chapter.



*Required access rights: Start Worklists*

### 3.1 Menus and Symbols



*The following alphabetic sorted tables describe all various menu items. Several menu items are enabled only when you can use them.*

#### 3.1.1 General Functions

Category	Function	Symbol	Description
Edit	OK		The input/change is applied and the corresponding dialog is closed.
Edit	Cancel		The input/change is <b>not</b> applied and the corresponding dialog is closed.
Edit	Redo		With this function, you can redo the changes previously made.
Edit	Undo		With this function, you can undo the previous changes.
Help	Help		Shows the on-line help.
Keyboard	Ctrl		Simulates the <i>Ctrl</i> key on your keyboard. If you select this function, you can select several non-consecutive items in a list.
Keyboard	Shift		Simulates the <i>Shift</i> key on your keyboard. If you select this function, you can select several consecutive items in a list.
Search	Scroll buttons (active in case of multiple page documents)		Jump to the previous/next line.

## Basic Functions

### Menus and Symbols





Category	Function	Symbol	Description
Search	Scroll buttons (active in case of multiple page documents)		Jump to the previous/next page.
Search	Scroll buttons (active in case of multiple page documents)		Jump to the first/last page.
Selection	Select All		This function selects all shown items in a list.
Selection			This symbol indicates that the corresponding function is <b>not</b> selected. (dark green)
Selection			This symbol indicates that the corresponding function is selected. (light green)

Table 3-1: General

## 3.1.2 Functions of the Menu and Selection Dialog File



Shows a selection dialog (see chapter 3.6.3 on page 3-24) for the following functions. These are the same functions as in the menu **File**.

Function	Symbol	Description	Chapter
Close		Closes the active document.	-
Exit		Terminates the program.	-
New		Shows a selection dialog to create new document (e. g. assays, worklists or reports).	chapter 3.2.1 on page 3-10
New Work-list		Opens the Set-Up Panel dialog to create a new worklist.	chapter 4.4 on page 4-10 + chapter 5.3 on page 5-13
Open		Shows a selection dialog to open a document.	chapter 3.3.1 on page 3-11
Print		Prints the active document (e. g. worklist, report).	chapter 3.5.1 on page 3-16
Print Pre-view		Shows the active document as print preview.	chapter 3.5.3 on page 3-20
Print Setup		Defines the printer and printing options.	chapter 3.5.2 on page 3-18
Save		Saves the active document (e. g. worklist, report).	chapter 3.4 on page 3-14
Save as		Saves active document (e. g. worklist, report) under a new name.	chapter 3.4 on page 3-14
Recent Pro-tocols		Shows the last opened and already saved assay protocol files for selection.	-
Recent Results		Shows the last opened and already saved result files for selection.	chapter 4.9.3 on page 4-65
Recent Worklists		Shows the last opened and already saved worklists for selection.	-

*Table 3-2: Menu and selection dialog File*



### 3.1.3 Functions of the Menu Edit

The functions of the menu Edit can only be used if a worklist is active.














Function	Symbol	Description	Chapter
Export Archive	 Export Archive	Exports archiving information as file. Not used.	-
Load Additional Tips		Allows the reloading of disposable tips.	chapter 4.7.6.1 on page 4-43
Lot Specific Values		Opens the Lot Specific Values dialog to show or edit the required reagents information.	chapter 4.5 on page 4-11
Optimise	 Optimise	Optimises the schedule of the defined worklist.	chapter 5.5.1 on page 5-32
Panel Definition	Edit Panel ...	Opens the Set-up Panel dialog to edit the current worklist. This function is also called Edit Panel	chapter 4.4 on page 4-10
Panel Options	Edit Options ...	Opens the Worklist Options dialog to change worklist processing options. This function is also called Edit Options	chapter 5.4 on page 5-24
Start		Opens the Load dialog to allocate the required resources. After that, a run using the current worklist will be started.	chapter 4.7 on page 4-28
Stop		Pauses the current run. The run can be continued again and one or several plates can be removed from processing. Or the entire run can be aborted completely.	chapter 4.8.5 on page 4-55
Unload Finished Plates		Allows the unloading of fully processed plates before the end of the run	chapter 4.10.1.2 on page 4-67

Table 3-3: Menu Edit

### 3.1.4 Functions of the Menu and Selection Dialog Utilities



Function	Symbol	Description	Chapter
Export Results		Each time a (*.res) result report is calculated and displayed on the screen, you can decide to export it.	chapter 6.1.4.1 on page 6-11
Log-Off/ Log-On		Allows to change the user. If the system has been started by one user and another user wants to take over, the second user should log-in under his/her own user name. To do so, it is not necessary to shut down the system and restart it.	-
Maintenance		Allows to select and execute programmed maintenance jobs.	chapter 8.5 on page 8-10
Options		Definition of software parameters (e. g. user access rights, laboratory details, preferences, directories, file polling, ASTM).	chapter 7.1 on page 7-1
Patient Details		Opens the complete Patient Editor dialog to view or edit patient data.	chapter 5.2 on page 5-4
Present Carriers		Manual plate control. Not recommended for normal use.	chapter 5.5.3 on page 5-38
Scanner		Allows to choose the track where the system will accept the next rack. Click on the desired track in the Select a Track dialog. <b>Note:</b> Double lane racks can only be inserted in every 2 <sup>nd</sup> track (the software will reject rack otherwise). <b>See warnings below.</b>	-
Select Language		Allows to change the software language. Only visible when no window is opened.	chapter 5.9 on page 5-53
Selftest		Performance of a self test (initialization).	chapter 5.1 on page 5-1
System Setup		Definition of instrument parameters.	chapter 7.2 on page 7-11





Function	Symbol	Description	Chapter
System Utilities		Manual plate control. Not recommended for normal use.	chapter 5.5.3 on page 5-38
Turn Scanner Off		Switches the loading bay bar code scanner off. <b>Note:</b> The loading bay bar code scanner moves back to its park position. <b>See warnings below.</b>	-
Turn Scanner On		Switches the loading bay bar code scanner on. <b>See warnings below.</b>	-
Verify		Checks the photometer using the reader verification plate.	See 'Reader Verification Plate Manual'
Volume Offset		Definition of pipetting volume correction. Only used for development and manufacturing.	-

Table 3-4: Menu Utilities



***Never use the loading bay as storage space! The moving bar code scanner could be damaged or stored objects could be upset.***



***Only load or unload on the indicated lane. Wait for a load/unload message! Wait until the bar code scanner stands idle!***



***Never reach on the right side of the bar code scanner into the loading bay! The bar code scanner could crash into your hand, when it drives back.***

### 3.1.5 Functions of the Menu and Selection Dialog Windows



Function	Symbol	Description	Chapter
Arrange Icons		Stacks all minimized windows and aligns them from the lower left to the upper right of the workspace.	-
Cascade		Stacks all windows and aligns them from the upper left to the lower right of the workspace.	-
New Window		Shows the active document in a new window. The new window is only a new <b>view</b> of the document and <b>not</b> a new document.	-
More Entries		Shows the name of all opened documents/windows. Select one entry to move the document on the top.	-
Tile		Stacks all windows and aligns them in rows.	-

Table 3-5: Menu and selection dialog Windows

### 3.1.6 Functions of the Menu and Selection Dialog Help






Function	Symbol	Description	Chapter
About Elisis Duo		Shows the version number of the <i>Elisis Duo</i> software.	-
Context Sensitive Help		Shows the on-line help of the selected function (when available).	-
Help Topics		Shows the on-line help (when available).	-

Table 3-6: Menu and selection dialog Help

## 3.2 New

### 3.2.1 Functions of the Selection Dialog New







Function	Symbol	Description	Chapter
Assay		Opens the <b>Select Assay Protocol Type</b> dialog to create a new assay.	see "Assay Programming Manual"
Job List		Shows a list of patient IDs with the assays to be performed for each patient, i.e. patient data and test orders already stored in the system and not yet processed. This corresponds to the data currently available in the <b>Patient Editor</b> dialog. This function is useful because it allows you to know rapidly if there is any "back log" or if there is a lot of work remaining to be done. This <b>Job List</b> can be printed.  This <b>Job List</b> is different from the <b>Job List</b> displayed in the <b>Worklist</b> window. The <b>Job List</b> displayed in the <b>Worklist</b> window shows the patient IDs and assays included in that worklist	-
Patient Results Report		Opens the <b>Patient Results</b> dialog to create a patient result report.	(see chapter 5.7 on page 5-48)
QA Analysis Report		Opens the <b>Q.A. Analysis</b> dialog to create a QA analysis report.	chapter 5.8 on page 5-52
Spectral Response		If you select <b>Spectral Response</b> , the system asks you to load a test plate. The photometer then perform readings of the 96 wells on the plate using <b>all</b> the installed filters. From these readings, the system produces a spectral response curve. Suggested test and reference filters are displayed on the screen. Double-click on a specific well to display the curve recorded for this well. A further double-click shows the overview again.	-
Worklist		Opens the <b>Set-Up Panel</b> dialog to create and start a new worklist.	chapter 4.4 on page 4-10

Table 3-7: Selection dialog New

### 3.3 Load (Open)



With the function **Open**, results, worklists, event logs etc. stored/saved on the PC can be reloaded and displayed. In a first step, the type of file is selected, in the second step, the file itself is selected.

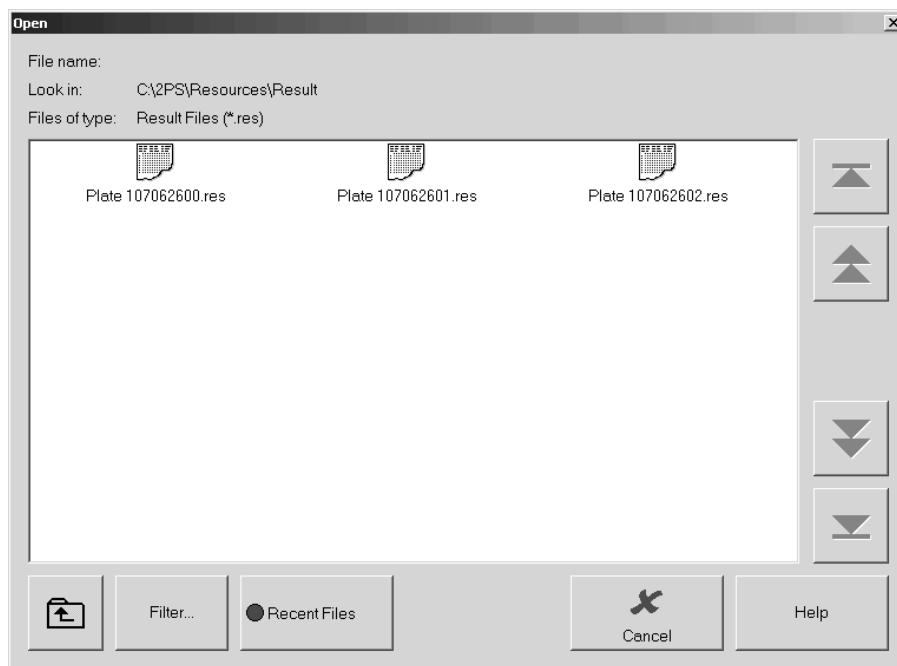
#### 3.3.1 Functions of the Selection Dialog **Open**

Function	Symbol	Description	Chapter
ASCII Patient Information		Shows the <b>Open</b> dialog to open ASCII patient information files.	chapter 6.1.3 on page 6-5
Assay Protocol Files		Shows the <b>Open</b> dialog to open assay protocol files.	see "Assay Programming Manual"
Event Log Files		Shows the <b>Open</b> dialog to open event log files.	chapter 4.6.6 on page 4-23
Reagent Layout Files		Shows the <b>Open</b> dialog to open reagent layout files.	-
Result Files		Shows the <b>Open</b> dialog to open result files.	chapter 4.9.3 on page 4-65
Selftest Reports		Shows the <b>Open</b> dialog to open selftest report files.	chapter 5.1 on page 5-1
Spectrum Files		Shows the <b>Open</b> dialog to open spectrum files.	-
Verification Reports		Shows the <b>Open</b> dialog to open verification report files.	-
Worklist Files		Shows the <b>Open</b> dialog to open worklist files.	chapter 5.3.4 on page 5-23

Table 3-8: Selection dialog **Open**

#### 3.3.2 Open a File

With the function **Open**, results, worklists, etc. stored on the PC can be reloaded and displayed. For this purpose, the **Open** dialog is selected. In this dialog, the storage position (folder) and the file can be selected.



*Figure 3-1: Open dialog*




Function	Symbol	Description
File name		-
Files of type		Shows the file type (see chapter 7.1.6.1 on page 7-9)
Filter		<p>With this function, the number of files displayed can be limited.</p> <p>After pushing the button, the <b>Edit Text</b> dialog (see chapter 3.6.1 on page 3-21) is opened. After the entry, only those files containing the entered text are displayed. The filter ignores capitalisation.</p> <p>Example:  Filter input: 0706  Displayed files: Plate07062001, Plate07062701</p>
Folder up		<p>With this button, you can move to the superordinate folder.</p> <p>Example:  C:\Programme\Human\System  =&gt; C:\Programme\Human</p>
Look in		Shows the selected or defined folder (see chapter 7.1.6 on page 7-8) to open the file.
Recent Files		<p>After clicking on this function, only files are displayed which have already been opened recently. If this function is clicked on again, all files are displayed again.</p> <p>This function has priority over the <b>Filter</b> function.</p>

Table 3-9: Functions of the Open dialog

## 3.4 Save

### Save



With the function **Save**, results, worklists, etc. can be saved on the PC. If no file has been assigned up to now, the function **Save as** is opened automatically.

### Save as

With the function **Save as**, results, worklists, etc. can be saved on the PC. For this purpose, the **Save as** dialog is opened. Here, the storage location (folder) and the file name can be defined. If a file with the entered file name already exists, **Elisys Duo** software requires whether to overwrite the existing file.

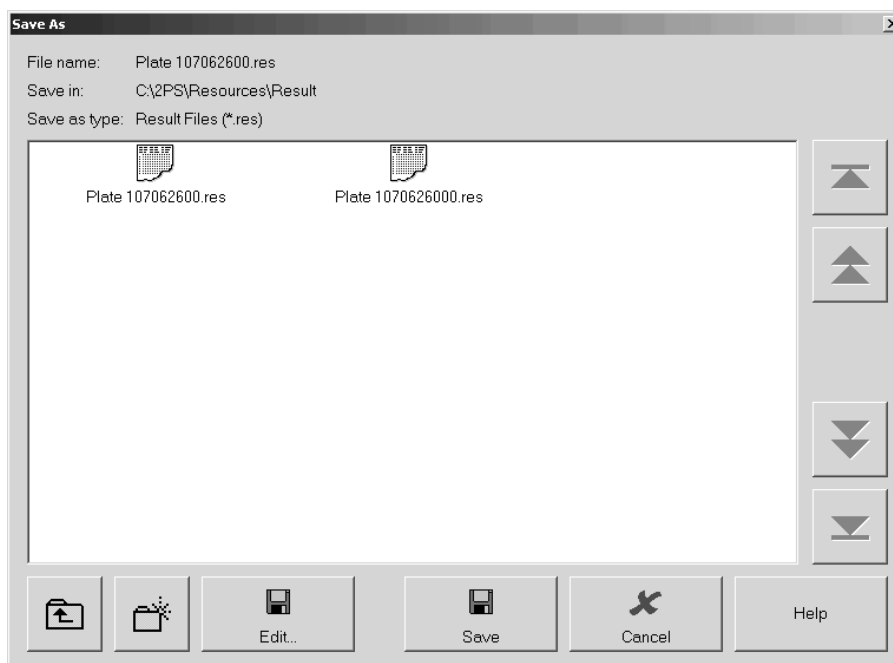


Figure 3-2: Save as dialog




Function	Symbol	Description
Edit		After clicking on the <b>E d i t</b> button, the <b>E d i t T e x t</b> dialog (see chapter 3.6.1 on page 3-21) is displayed. Here, a new file name can be entered.
File name		Shows the existing, or automatically generated file name
Folder up		With this button, you can move to the superordinate folder. Example: C:\Programme\Human\System => C:\Programme\Human
New folder		By means of this button, a new folder can be created. The name is entered in the <b>E d i t T e x t</b> dialog (see chapter 3.6.1 on page 3-21).
Save		After clicking on the <b>S a v e</b> button, the file is saved with the entered file name.
Save as type		Shows the file type (see chapter 7.1.6.1 on page 7-9)
Save in		Shows the selected or defined folder (see chapter 7.1.6 on page 7-8) to save the file.

Table 3-10: Functions of the *Save as* dialog

### 3.5 Print on the Printer

With the function **Print**, results, worklists, etc. can be printed with the printer. Before printing, there is the possibility to select the printer, to adapt the printer settings and to view the printout as preview on the screen.

#### 3.5.1 Print



With the function **Print**, results, worklists, etc. can be printed directly.

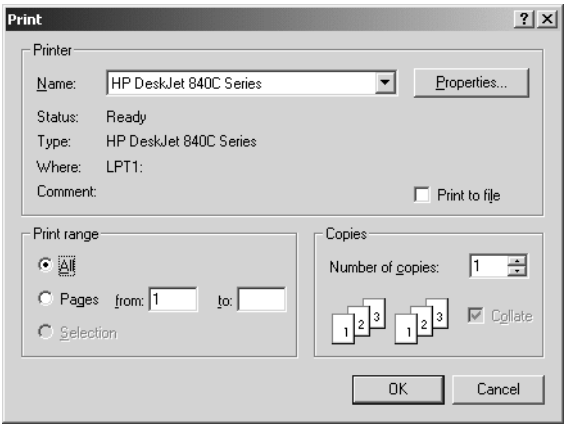


Figure 3-3: Print dialog

#### Printer Area

Function	Description
Name	Displays the standard printer. With the list, another printer can be selected.
Print to file	After the selection of this function, a file is created instead of a printout. The file is a pure print file and cannot be opened with the <b>Elisys Duo</b> software.
Properties	Shows the properties dialog of the selected printer. See printer manual for detailed information an settings.
Status/Type/Where	Information about the printer.

Table 3-11: Functions of the Print dialog - Printer area

**Print range  
Area**

Function	Description
All	Prints the complete document (results, assay etc.).
Pages	Prints the specified pages of the document.
Selection	Prints the marked part of the document.

*Table 3-12: Functions of the Print dialog - Print range area***Copies Area**

Function	Description
Collate	If more than one copy is to be printed, you can specify here whether the printouts are to be collated.
Number of copies	By means of this function, the number of copies can be set.

*Table 3-13: Functions of the Print dialog - Copies area*

### 3.5.2 Print Setup



With the function **Print Setup**, the printer to be used can be selected and preconfigured. The settings are applicable for all subsequent printouts.

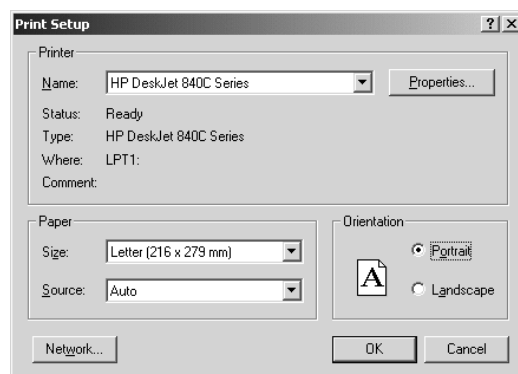


Figure 3-4: Print Setup dialog

#### Printer Area

Function	Description
Name	The standard printer is displayed. With the list, another printer can be selected.
Print to file	After the selection of this function, a file is created instead of a printout. The file is a pure print file and cannot be opened with the <b>Elisys Duo</b> software.
Properties	Shows the properties dialog of the selected printer. See printer manual for detailed information and settings.
Status/Type/Where	Information about the printer.

Table 3-14: Functions of the Print dialog - Printer area

#### Paper Area

Function	Description
Size	Allows the selection of the size of the paper to be used.
Source	Allows the selection of the paper tray where the selected paper lays in.

Table 3-15: Functions of the Print Setup dialog - Paper area

## Orientation Area

Function	Description
Landscape	The selected paper is used crosswise.
Portrait	The selected paper is used on edge.

*Table 3-16: Functions of the Print Setup dialog - Orientation area*

### 3.5.3 Print Preview



This function allows a preview of the printout on the screen. In this way, for example printer presettings can be checked.

Function	Description
Close	Close the print preview.
Next Page	Shows the next page.
Prev Page	Shows the previous page.
Print	Allows the printout of the preview (see chapter 3.5.1 on page 3-16).
Two Page	Shows two pages on the screen.
Zoom In	Scale up the shown page.
Zoom Out	Scale down the shown page.

*Table 3-17: Functions of the Print Preview dialog*



## 3.6 Edit and Selection Dialogs

### 3.6.1 Edit Text Dialog

The Edit Text dialog allows the convenient entry of text on a touch screen monitor. For that, a "keyboard" is displayed on the screen for the entry of the text.

The entry itself is displayed in a separate text area. Next to this text area, the relevant purpose is displayed (e.g. password).



Figure 3-5: Edit Text dialog (example: password dialog)






Function	Symbol	Description
Cancel		The entry is <b>not</b> imported and the Edit Text dialog is closed.
Delete		Pushing the Delete button deletes the character or digit on the left side of the cursor.
Left		Pushing the left button makes the cursor jumping to the left by one figure.
OK		The entry is applied and the Edit Text dialog is closed.
Right		Pushing the right button makes the cursor jumping to the right by one figure.
Shift		Shift switches to upper case for the next typed character only.
Shift Lock		<p>Shift Lock switches between upper and lower case, respectively between numbers or special characters.</p> <ul style="list-style-type: none"><li>• Not activated: Numbers or special characters can be used, which are displayed in the lower part of the corresponding button, as well as lower case characters.</li><li>• Activated: Special characters can be used which are displayed in the upper part of the corresponding button and all characters in upper case.</li></ul>

Table 3-18: Functions of the Edit Text dialog

### 3.6.2 Edit a Number Dialog

The Edit a Number allows the convenient entry of numbers on a touch screen monitor. For that, a "numerical keyboard" is displayed on the screen for the entry of the numbers.

The entry itself is displayed in a separate text field.

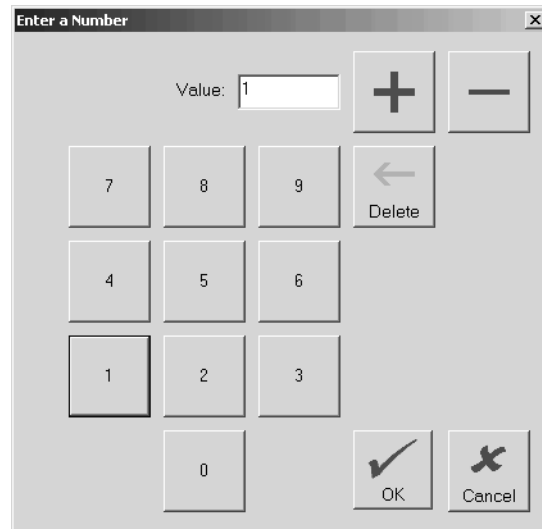


Figure 3-6: Enter a Number dialog






Function	Symbol	Description
Cancel		The entry is <b>not</b> applied and the Edit a Number dialog is closed.
Delete		By pushing the button, the digit on the left side of the cursor is deleted.
Minus		The displayed value is decreased by one.
OK		The entry is applied and the Edit a Number dialog is closed.
Plus		The displayed value is increased by one.

Table 3-19: Functions of the Edit a Number dialog

### 3.6.3 Selection Dialog

Selection dialogs allow you to select a special function. The use of the selection dialogs is very easy. Search your desired function. If necessary, use the arrow buttons (see chapter 3.1.1 on page 3-1). Click on the desired function.

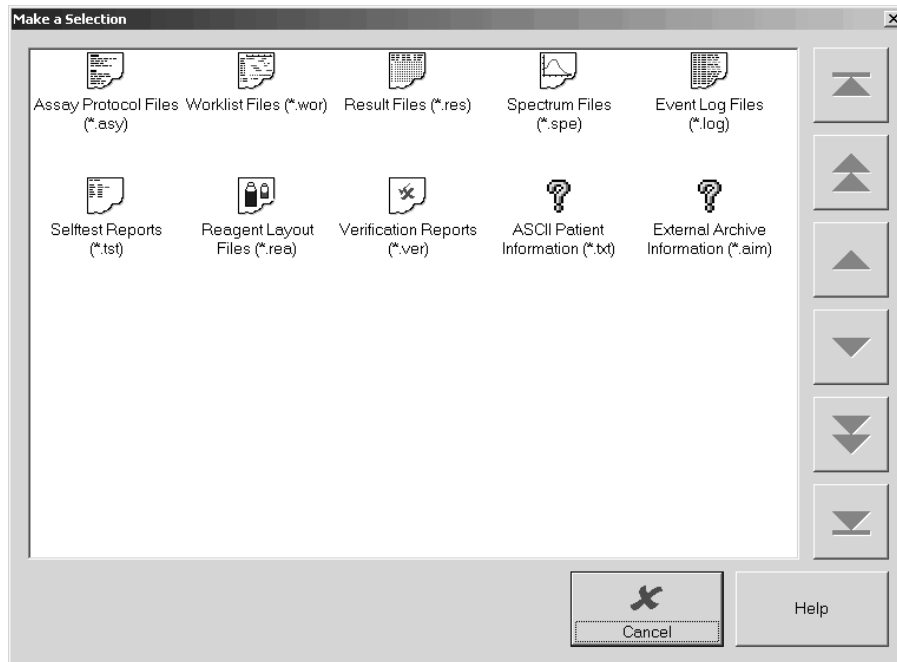


Figure 3-7: Make a Selection dialog (e.g. Open)

## 4 Use of the System

In this chapter, the process of a test case from switching on till switching off the system for a "normal" user is described with the right to start a worklist.



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*Required access rights: Start Worklists*

---

The basic functions of the **Elisys Duo** software are described in chapter 3 on page 3-1.

Additional functions for "normal" users and for users with additional rights are described in chapter 5 on page 5-1.



---

*Do not use an external keyboard for normal use of the **Elisys Duo** system.*

---

## 4.1 Brief Sequence Plan

<b>Start-up</b>	<ul style="list-style-type: none"> <li>• Maintenance</li> <li>• Switch on</li> <li>• Start <b>Elisys Duo</b> software</li> </ul>	chapter 4.2 on page 4-3
<b>Load Samples and Assign Assays</b>	<ul style="list-style-type: none"> <li>• Load samples</li> <li>• Assign assays</li> </ul>	chapter 4.3 on page 4-5
<b>Create a Worklist</b>	<ul style="list-style-type: none"> <li>• Check plates</li> <li>• Check assays</li> <li>• Check samples</li> </ul>	chapter 4.4 on page 4-10
<b>Lot Specific Values</b>	<ul style="list-style-type: none"> <li>• Enter batch numbers</li> <li>• Enter assay protocol parameters</li> </ul>	chapter 4.5 on page 4-11
<b>The Worklist Window</b>	<ul style="list-style-type: none"> <li>• Check worklist</li> </ul>	chapter 4.6 on page 4-14
<b>Start Worklist</b>	<ul style="list-style-type: none"> <li>• Load samples</li> <li>• Load reagents</li> <li>• Load unstable reagents</li> <li>• Load dilution plates</li> <li>• Load tip racks</li> <li>• Fill wash buffer and clean fluid</li> <li>• Fill system liquid</li> <li>• Load test plates</li> </ul>	chapter 4.7 on page 4-28
<b>Processing the Run</b>	<ul style="list-style-type: none"> <li>• Pre-run checks</li> <li>• Steps of a typical test run</li> <li>• What you can do</li> <li>• System/Pipetting errors</li> <li>• System pause</li> </ul>	chapter 4.8 on page 4-49
<b>End of Run/Result Report Window</b>	<ul style="list-style-type: none"> <li>• Structure</li> <li>• Result interpretation</li> <li>• Editing/Recalculating the results</li> <li>• Save/Open the result report</li> <li>• Print the result report</li> <li>• Export the results</li> </ul>	chapter 4.9 on page 4-58
<b>Unloading</b>	<ul style="list-style-type: none"> <li>• Unload test plates</li> <li>• Unload sample racks</li> <li>• Unload reagent racks</li> <li>• Unload tip racks and dilution plates</li> <li>• Unload other resources</li> <li>• Unload waste disposal</li> </ul>	chapter 4.10 on page 4-67
<b>Shut-down</b>	<ul style="list-style-type: none"> <li>• Maintenance</li> <li>• Terminate <b>Elisys Duo</b> software</li> <li>• Shutdown operating system</li> <li>• Switch off</li> </ul>	chapter 4.11 on page 4-71

## 4.2 Start-up



*Please follow closely the steps contained in the individual instructions to achieve a perfect function of the instrument.*

### Maintenance

- Check the level of system liquid in the system liquid container. If low, refill it.
- Check the level of waste liquid in the waste liquid container. If full or nearly full, empty and decontaminate it.  
Dispose waste liquid in accordance with legal regulations for biological hazardous waste.
- Check pipettor tubing and syringe for air bubbles or leakages as these can cause pipetting errors.

See also chapter 8.2.1 on page 8-3.

### Procedure

#### Switch on:

1. Close the cover.
2. Switch on the instrument.  
The system is initialised and the integrated PC starts the Windows operating system.

#### Start *Elisys Duo* software and log-on:

3. Double-click on the program icon to start the **Elisys Duo** software.  
The **Elisys Duo** software shows the Log-On dialog:

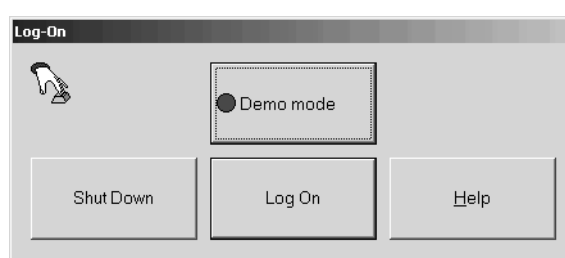


Figure 4-1: Log-On dialog

Function:	Description:
Log On	Shows a dialog to enter the user name.
Demo mode	Starts the <b>Elisys Duo</b> software without connection to the instrument. The demo mode can be used to check assays or processes. See chapter 5.10 on page 5-54.
Shut Down	Terminates the program.

Help	Shows the on-line help.
------	-------------------------

4. Click on the **Log On** button.  
The **Elisys Duo** software shows the **EditText** dialog to enter your user name (see chapter 3.6.1 on page 3-21).  
The user name entered when logging in will automatically appear in the **Operator** field in the selftest report and also in the header of the result files and result reports. It ensures a better traceability of tests performed.
5. Click on the **OK** button.  
The **Elisys Duo** software shows the **EditText** dialog again to enter the password.
6. Enter the password (if necessary) or let the field blank.  
Users with password could have other rights than users without password (see chapter 7.1.1 on page 7-1)
7. Click on the **OK** button.  
The **Elisys Duo** performs a selftest.



## 4.3 Load Samples and Assign Assays

In this section, it is described how samples with or without bar code can be loaded into the system and how they can be assigned to one or several assays.

### Information about used As- says

Before processing an assay (especially if it is the first time you are using this assay), you may want to review the various steps to be performed, the task sequence, the incubation times, the reagents used, etc.

To do this, open and print the assay file as described in chapter 3.3 on page 3-11 and chapter 3.5 on page 3-16. For more details about assays, see "Assay Programming Manual".

### 4.3.1 Load Samples



***Never use the loading bay as storage space! The moving bar code scanner could be damaged or stored objects could be upset.***



***Only load or unload on the indicated lane. Wait for a load/unload message! Wait until the bar code scanner stands idle!***



***Never reach on the right side of the bar code scanner into the loading bay! The bar code scanner could crash into your hand, when it drives back.***



***Do not touch the bar code scanner while loading a rack!***



***Do always push in the racks into the rack system with the handle or pull it out again with the handle.***



***Insert the racks carefully to avoid tipping over and spilling of bottles or tubes.***



***In one rack, only tubes of the same type may be used to avoid problems during the aspiration of liquids. The tube type must be approved for the relevant rack.***



***Use only exact modelling of tubes to ensure correct tracking.***



*Never load more than one rack at the same time! For proper bar code identification the racks must be loaded one after the other, as indicated by the LEDs.*



*To avoid clots, the samples should have been treated accordingly (e.g. centrifuged) prior to the use in the **Elisys Duo** system.*

#### Procedure

1. Place the sample tubes in the sample racks.
  - **Bar coded samples:**  
Make sure that the bar code labels on the individual samples face right so that they can be scanned by the bar code reader when the rack is inserted.
  - **Non bar coded samples:**  
If you are using non bar coded sample tubes **and** you want to use the **Auto Arrange** function to allocate samples, be sure to place the samples in the racks in the order that will be used by the system to allocate the samples (see chapter 4.7.2 on page 4-34).
2. Click on the **Utilities** button (see chapter 3.1.4 on page 3-6).
3. Click on the **Turn Scanner On** button (see chapter 3.1.4 on page 3-6).
4. Insert the first rack on the lane marked by the LED illuminated permanently. Place the rack in front of the lane and then push evenly up to the limit stop (with the tappet in the contact opening on the rear panel).  
The rack bar codes and the individual sample bar codes are read. If the rack has been inserted properly all the way, the LED goes off for this position, and turns on at the next position that can be loaded.
5. Enter ID for non bar coded samples and assign assays to all loaded samples (see chapter 4.3.2 on page 4-6).
6. Insert the other sample racks in the same manner.



#### Troubleshooting

- Troubleshooting while Loading Samples (see chapter 9.2.1 on page 9-15)

### 4.3.2 Assign Assays to the Samples (Tabular Patient Editor)

#### Pre-Defined Assays

In this chapter, it is assumed that the tests are performed using pre-defined assays supplied by the manufacturer.

However, the **Elisys Duo** system also allows users to create and use their own assays (see 'Elisys Duo - Assay Programming Manual')

#### Processing Several Assays

The **Elisys Duo** instrument and software allow the user to process different assays in the same test run. In most cases, a different test plate will be used for each assay. This is described in this section.

However, the **Elisys Duo** system is flexible and also allows the user to combine several compatible assays on the same test plate (see chapter 5.3.3 on page 5-19).

**Procedure**

Each time you load a sample rack as described in chapter 4.3.1 on page 4-5, the following tabular Patient Editor dialog is automatically displayed:

	Assay Demo 2	Patient IDs	Assay Demo 1	Assay Demo 2	<None>
1. 00075448	✓	00075448	✓	✓	
2. 00075435	✓	00075435	✓	✓	
3. 00003463		00003463	✓		
4. 00003460		00003460	✓		
5. 00075438	✓	00075438		✓	
6. 00075417	✓	00075417		✓	
7. 00003458		00003458			
		00075443			
		00075387			
		00075442			
		00003459			
		<None>			
		<None>			
		<None>			
		<None>			
		<None>			
		<None>			

Figure 4-2: Tabular Patient Editor dialog (with patient IDs and assigned assays)



The system displays one dialog per inserted rack (if you insert three racks, the system will display this dialog three times).



This dialog is not displayed if you use the **Elisys Duo** software in demo mode. In this case, please refer to the manual procedure with the complete Patient Editor dialog (see chapter 5.2 on page 5-4).

**Bar coded samples:**

If you are working with bar coded samples, column 1 shows the Patient IDs as read on the bar codes.

**Bar coded and non bar coded samples:**

If you have both bar coded and non bar coded samples on the same rack, the bar coded positions in column 1 will be filled while the non bar coded positions will be blank. You have to enter the (non bar coded) Patient IDs manually in column 1:

1. Select the empty Patient ID field.  
**Do not remove or exchange any of the bar coded samples** (the system compares successive readings).
2. Enter the correct patient ID.



The entered patient ID must be unique! If non-unique patient IDs are used (e.g. same ID for different persons at different worklists), the sample data-

*base is incorrect. In this case, features like sample history or sample result report must not be used.*

---



*Recheck entered patient ID and original patient ID!*

---

A blank position can also indicate either that a position is empty (no test tube was inserted) or that the system has not been able to read the sample bar code correctly (see chapter 9.2.1.1 on page 9-15).

---



*In the results, all manually entered patient IDs will be flagged ("ManID" flag).*

---

#### **Non bar coded samples:**

If you are working with non bar coded samples, you have to enter the **Patient IDs** manually in column 1 (see above). If you have a lot of non bar coded samples to process, you may prefer to close this dialog box (click on the **Close** button) and do the assay assignments using the manual procedure described in chapter 5.2 on page 5-4.

#### **Assign one or more assays to each sample:**

1. Click on the button over the first free column.
- 



*The left side of the dialog shows you an enlarged view of the red marked area on the right side.*

---

2. Select the assays in the selection dialog (see chapter 3.6.3 on page 3-24) to be processed in this test run. If you want to assign more assays, additional columns will be automatically displayed.
3. Select the cell in the assay columns for the samples who are to be tested with the assay you selected in the corresponding drop-down list.  
Use the green arrow buttons to scroll the screen.
4. Click on the **Close** button to close the tabular **Patient Editor** dialog.  
Never use the x button in the top right-hand corner of the dialog to close it - entered data would not be retained.
5. If you inserted more than one rack, the system displays the dialog for the next rack (it may take a little while to show on the screen). Repeat the procedure for each rack.

#### **Troubleshoot- ing**

- **Unreadable Bar Codes** (see chapter 9.2.1.1 on page 9-15)

### 4.3.3 Import Patient Data and Linked Assays through Host Connection

If the **Elisys Duo** system is connected to a host computer, patient data can be downloaded to the system via this connection. These downloads can be requested by the user or performed automatically as described in chapter 6.1.2 on page 6-3 and chapter 6.2.2 on page 6-16. The downloaded data can include the patient details (ID Code, Name, Birth date, Sex) and the tests/assays required for each patient if these have already been assigned (at the host computer level).

#### Procedure

##### If the data was imported before the racks were loaded:

If the rack(s) you inserted correspond to a test order that has already been imported into the **Elisys Duo** system, the tabular **Patient Editor** dialog will be automatically displayed with all the appropriate fields already filled in.

1. Just check that everything is correct and click on the **Close** button.  
Never use the x button in the top right-hand corner of the dialog to close it - entered data would not be retained.
2. If you have inserted more than one rack, the tabular **Patient Editor** dialog corresponding to the next rack will be displayed. Check it and close it.
3. Repeat the steps for each inserted rack.

##### If you have inserted the rack(s) before importing the data and are using ASCII file imports:

1. The tabular **Patient Editor** dialog is blank when it is displayed. Click on the **Close** button to close it. Repeat this step, if you had inserted more than one rack, to close all tabular **Patient Editor** dialogs.
2. Import the desired file as described in chapter 6.1.3.1 on page 6-7.
3. When you have obtained a message indicating that the file has been successfully imported, click on the **OK** button.
4. Pull out your sample racks and load them again.
5. Wait until the tabular **Patient Editor** dialog is displayed again with the appropriate data already entered. This may take some time.
6. Check that everything is correct and click on the **Close** button.
7. If you have inserted more than one rack, the tabular **Patient Editor** dialog corresponding to the next rack will be displayed. Check it and close it. Repeat this for each inserted rack.



---

*On importing multiple test order requests for the same sample, chapter 6.1.3.5 on page 6-10.*

---

##### If you have inserted the rack(s) before importing the data and are using an ASTM connection:

1. If you had checked the **Query Host For Test Orders** item in the **ASTM** dialog (see chapter 7.1.4 on page 7-5) the software will automatically interrogate the host for test orders related to the samples you have just loaded.
2. If you had not previously checked this item, you can check it now and then reload your samples.

## 4.4 Create a Worklist

A worklist is a work instruction for the **Elisys Duo** system. In the worklist, the sequence and the plates to be processed with the assigned assays are defined.

The following instruction describes how to generate and check a worklist which was automatically suggested by the **Elisys Duo** system. The **Elisys Duo** system suggests a worklist whenever you load samples as described in the previous chapters. If the assays included in the worklist belong to the same combination group and if the assay parameters (incubation time, shaking parameters...) are compatible, the system will automatically try to combine several assays on the same plate (provided the number of samples allows this). For more information on processing several assays on one plate, see chapter 5.3.3 on page 5-19.

If you want to edit a suggested worklist or generate a worklist yourself, please refer to chapter 5.3 on page 5-13.

### Procedure (Check Worklist)



1. Click on the menu item **New > Worklist** or the **New Worklist** button.

The **Elisys Duo** software shows the **Set-up Panel** dialog (see chapter 5.3.1 on page 5-15).

2. **Check the worklist** (see also chapter 5.3 on page 5-13):

- Click on the + sign of the first plate to open the complete plate/assays tree.
- **Check the assays!**  
If something does not work ok, please make the required changes.
  - Click on the + sign of the first assay to open the complete assay/samples tree.
  - **Check the assigned samples!**  
If something does not work ok, please make the required changes.
- Repeat the steps for all other assays on the selected plate.
- Repeat the steps for all other plates.

3. If everything works ok, click on the **OK** button. The **Elisys Duo** software shows the **Lot Specific Values** dialog (see chapter 4.5 on page 4-11). If something does not work ok, please make the required changes (see chapter 5.3 on page 5-13 and chapter 5.3.1 on page 5-15) and then click on the **OK** button.

Once the worklist is defined, the system checks all parameters and signals any error. Errors must be corrected before you start a run.

## 4.5 Lot Specific Values

After an internal check of the worklist, of the assay protocols and of the required reagents, the **Elisys Duo** software asks for required reagents (diluent, conjugate, substrate, stop solution, etc.), controls, standards, wash buffers and clean fluid in the Lot Specific Values dialog. The Lot Specific Values dialog also allows you to enter additional information for specific kit types.



*Reagents of different lots (but with same ID) are interchangeable for the software.*

For every used plate, an individual Lot Specific Values dialog is displayed. In this dialog, the lot specific values for all assays are listed, which are used on the relevant plate. The name of the plate is displayed in the title of the dialog (top left).

Figure 4-3: Lot Specific Values dialog (e.g. 'Plate 1' with two assays)

The Lot Specific Values dialog is subdivided into two areas:

**Batch Numbers** Parameters of the lot specific values.

**Assay Protocol Parameters** If the assay includes standards for which the concentration is batch dependent or if control value ranges are batch-dependent, these items are listed here with their respective batch-specific values/data (otherwise the list is blank).

#### Quality Control

To specify validation criterias for standards and controls it is necessary to add the tolerance range.

##### Procedure:

1. Click on the Add button.
2. Enter the label, tolerance range (see quality control certificate), and the unit.
3. Click on the OK button.
4. Repeat this steps for all standards and controls.

#### Functions

The following functions always refer to the highlighted line in one of the two lists:


Function	Symbol	Description
Assay registers		Via the assay registers, you reach the lot specific values belonging to the relevant assay.
Add Batch		Click this button if a QA of a reagent or sample will be made.  For example if you want to generate a <b>QA Analysis Report</b> (see chapter 5.8 on page 5-52) of replicates of reagents or of a reference sample this function can be used.  Enter the name of the new observable and assign the assay layout label being used by this.
Barcode		Shows the bar code of the kit.
Coatings		Click this button to enter coating criterias.
Edit Batch Name		With this function, you can edit the <b>Batch Name</b> , but need not because it is defined in the reagent database and in the assay definition.
Edit Expiry Date		With this function, you can enter the expiry date for the selected batch.
Edit Lot		Click this button to enter lot data for the selected batch.
Edit QA Label		Entering QA labels (e.g. NC, NC1, PC2, etc.) for controls allows you to follow the results obtained with a particular control over a period of time by compiling a <b>QA Analysis Report</b> (see chapter 5.8 on page 5-52).
Edit Target Value		Click this button to enter the target value for the selected batch.
Edit Tolerance		With this function you can enter a tolerance range for the selected batch.
Edit Units		With this function you can enter the unit of the tolerance range for the selected batch.
Remove Batch		Removes the highlighted reagent from the list.  This function delete the reagent only from the list and you can't enter the <b>Batch Number</b> etc.

Table 4-1: Functions of the Lot Specific Values dialog



## Troubleshooting

- Error Detection while creating Worklist (see chapter 9.3.1 on page 9-19)

## 4.6 The Worklist Window

The Worklist windows show all data of the generated worklist and the current process status during the start later on. With the buttons on the left side, the individual data can be displayed. Additionally, the menu **E d i t** is activated (see chapter 3.1.3 on page 3-5).

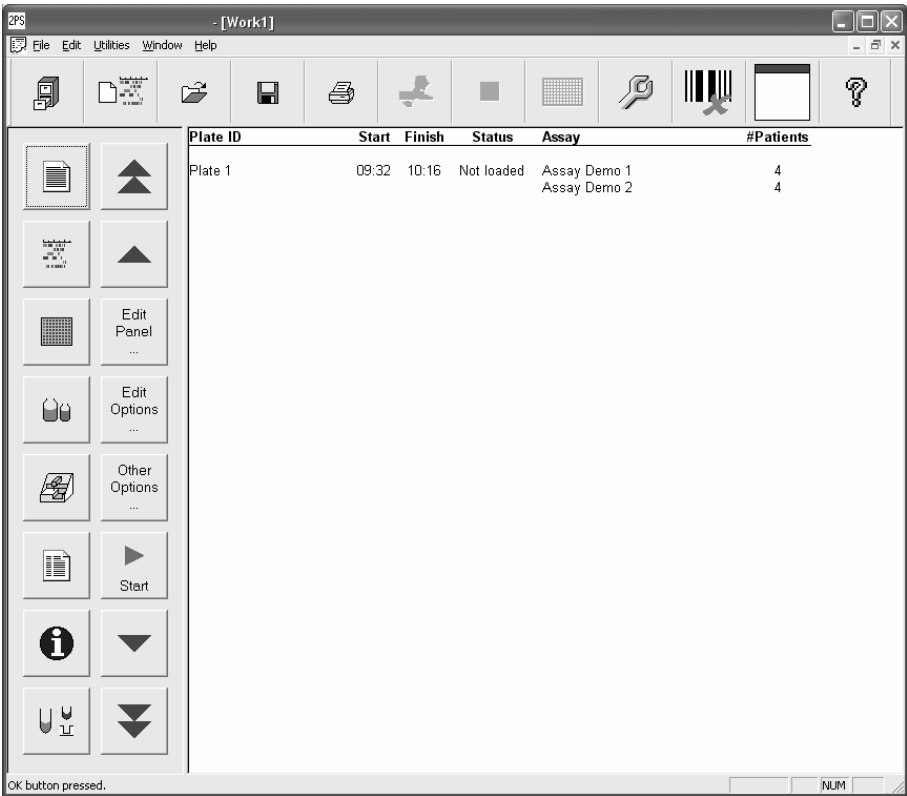






Figure 4-4: Worklist window - worklist parameters information

Function	Symbol	Description	Chapter
Worklist parameters		Shows worklist details (e.g. plate ID, start and finish time, load status, assays and amount of samples).	chapter 4.6.1 on page 4-16
Schedule		The schedule displays graphically the actions being performed (e.g. pipette, wash, incubate etc.).	chapter 4.6.2 on page 4-17
Plate layouts		Shows the plate layout (e.g. assays, controls, samples) of all plates.	chapter 4.6.3 on page 4-19
Reagent requirements		Shows all required reagents.	chapter 4.6.4 on page 4-20






Function	Symbol	Description	Chapter
System status		Shows the status of the system components (e.g. incubators, rack system etc.).	chapter 4.6.5 on page 4-22
Active event log		Shows a list of all steps of the run as they are performed. The screen is blank when viewed before the start of the run.	chapter 4.6.6 on page 4-23
Job list		Shows all samples and its assigned assays.	chapter 4.6.7 on page 4-27
Patient archiving information		Shows information about the sample archiving.	chapter 4.6.8 on page 4-27
Edit Panel	Edit Panel ...	Opens the Set-up Panel dialog box with editing options of the current worklist. This function is also called Panel Definition.	chapter 5.3.1 on page 5-15
Edit Options	Edit Options ...	Opens the Worklist Options dialog box to change worklist processing options. This function is also called Panel Options.	chapter 5.4 on page 5-24
Other Options	Other Options ...	Opens a selection dialog to select further options (e.g. lot specific values - see chapter 4.5 on page 4-11, or export archive etc.).	-
Start		Opens the Load dialog to allocate the required resources. After that, a run using the current worklist will be started.	chapter 4.7 on page 4-28

Table 4-2: Functions of the Worklist window

**Procedures**

1. Look for the worklist settings and/or change the worklist settings (see table 4-2 on page 4-15).
2. To start the worklist see chapter 4.7 on page 4-28.

### 4.6.1 Worklist Parameters

This window shows the parameters of the worklist (see chapter 4.6 on page 4-14) in the following columns:

Column	Description
Plate ID	List of defined plates and indication of the plate names.
Start	Start time of run. This is the time at which you have quit the <b>Set-up Panel</b> dialog by clicking <b>OK</b> and the worklist was displayed.
Finish	Time at the end of the run, calculated using the work steps and their duration.  Note: The actual finish time depends on when the run is actually started. The time displayed here allows you to calculate how long the run will take.
Status	Shows the status of each plate. If <b>Error</b> is displayed, see (see chapter 9.3.1 on page 9-19). Otherwise, you see <b>Not loaded</b> as long as the test plates have not yet been loaded. The status then changes to <b>Processing</b> and finally to <b>Finished</b> (or <b>Aborted</b> if the processing of that plate has been stopped and not resumed).
Assay	Shows the name of the respective assay file. If there are more than one assay on a given plate, all the names are listed one below the other.
#Patients	Shows the number of samples per plate (and per assay if there are more than one on the same plate) as defined in the worklist.

Table 4-3: Columns of the Worklist parameters window

## 4.6.2 Schedule

The **Schedule** shows how the test will actually be performed. This allows the user to get an accurate view of the duration of each step and the sequence in which they will be conducted, as well as how the system will combine the processing of all the plates that are to be processed in the same run (interlacing). It is therefore a good idea to check the **Schedule** before starting the run (the **Schedule** is also useful afterwards, when the run is being processed, to follow how the test run is executed and which step is currently being performed on which plate).

The schedule is displayed in two ways:

### Module Schedule (top):

Each strip or segment shows at which time each instrument module (pipettor, washer, colorimeter, incubator, plate transport unit) will be used for each plate. Each plate is depicted in a different color. The run time scale is on a horizontal line above the strips. When the test run is started, the vertical line on the left will move forward (towards the right), allowing the user to check at any given time what part of the run is currently being processed.

### Plate Schedule (bottom):

Each plate is shown as a horizontal strip. The various steps of the process (pipetting, incubation, reading, washing) are shown as segments on this strip (each step marked by a different color). As in the **Module Schedule** view, the time scale is at the top and the vertical line on the left will move forward once the run is started.

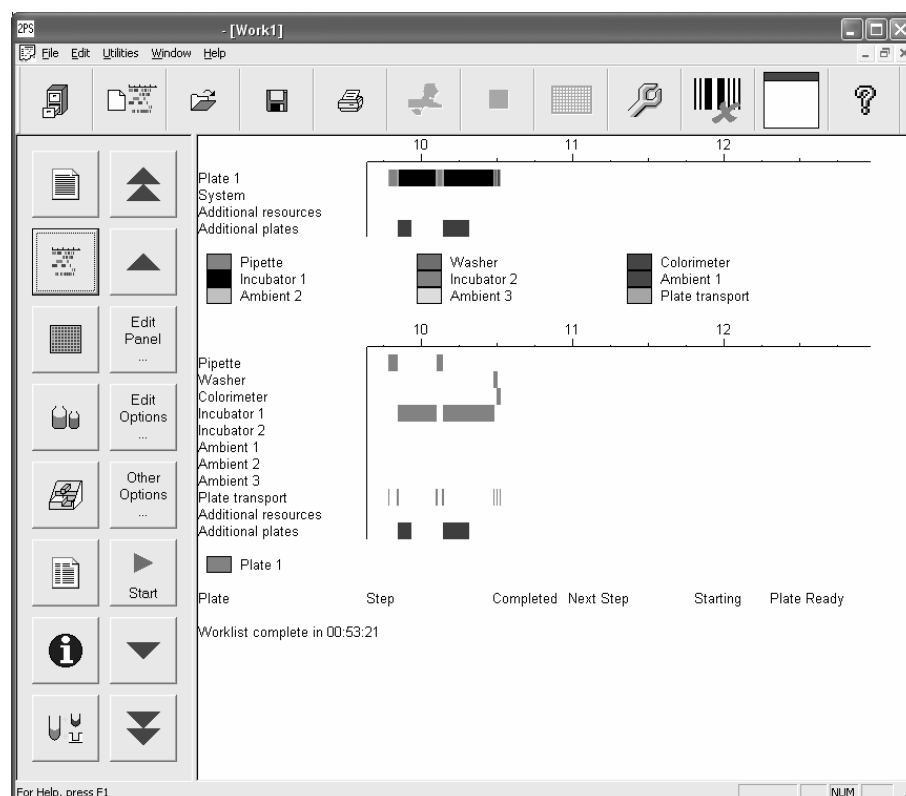


Figure 4-5: Worklist window - schedule

Below the strips, additional information is displayed:

	Description
System	Shows when the sample archiving operations will be performed.
Additional resources	Shows when additional resources such as tips or reagents are to be loaded. If such reloading is necessary, a line saying "Operator intervention required in X minutes" will also displayed.
Additional plates	Shows the time periods when it is possible to reload test plates (corresponds to periods when all the plates being processed are incubating).

Table 4-4: Additional information

When you click on a segments of the schedule view, a screen with detailed information about the respective assay step will be displayed. Clicking again on this screen will display again the complete schedule.



---

*When processing a run in Demo Mode (see chapter 5.10 on page 5-54) the run time displayed in the Schedule window will be accelerated, i.e. 1 second in the Schedule window = 1 minute in a real run.*

---

### 4.6.3 Plate Layouts

Selecting **Plate Layouts** will show the exact plate layouts. All plate layouts defined in the current worklist are displayed one below the other.

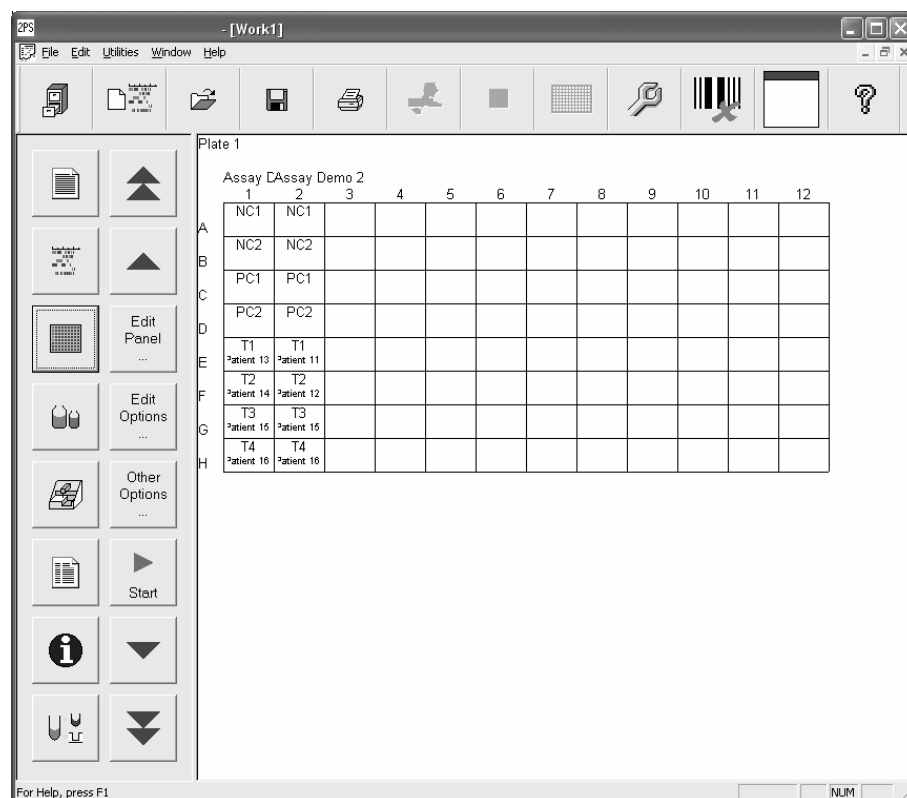


Figure 4-6: Worklist window - plate layouts

See chapter 5.3.1 on page 5-15 for used plate layout labels.

4.6.4 Reagent Requirements

Selecting Reagent requirements shows the list of all reagents required for the tests.

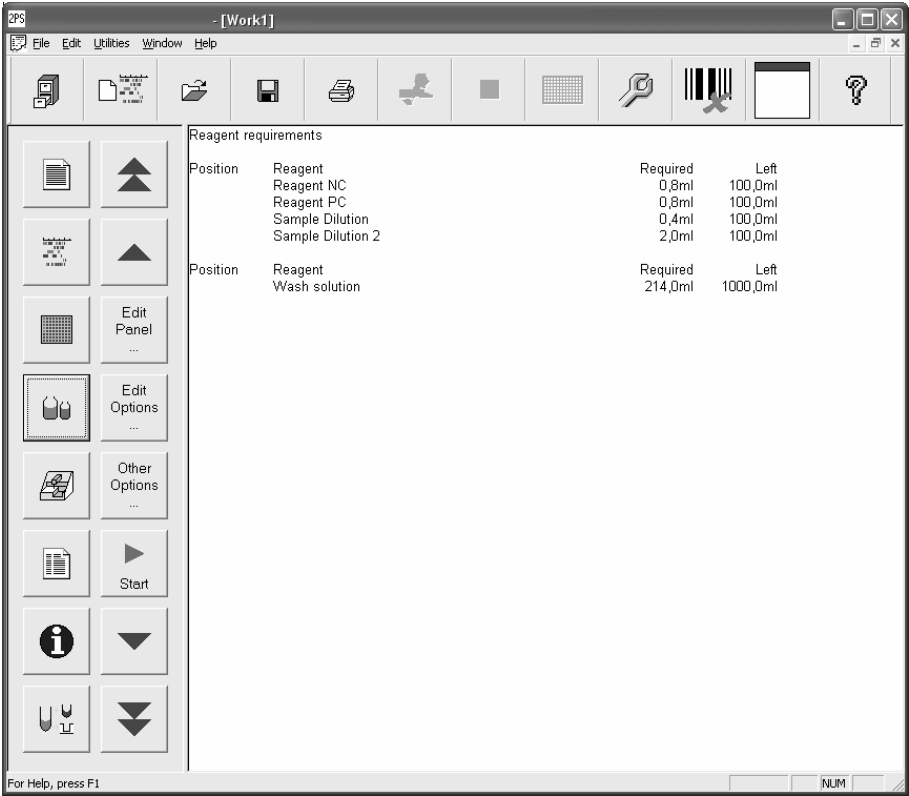


Figure 4-7: Worklist window - reagent requirements

This window shows the reagent information in the following columns:



Column	Description
Position	Indicates where each reagent has been loaded on the instrument. This column remains empty until all reagents are loaded and allocated (see chapter 4.7.3 on page 4-36).
Reagent	List of all the required reagent. The order of the list follows the order of the assays to be processed. Clean fluid and wash buffers are listed separately at the bottom.
Required	Volume of each reagent required for the run.
Left	Volume available. This entry will decrease as the run is being performed. By default, the volume that is displayed before the worklist begins and which will be used to calculate the available volume while the run is being performed is the volume of the respective reagent bottle <b>when full</b> . If you want the system to determine the exact volume that is <b>actually available</b> in the bottles, you have to enable the <b>Check reagent levels before a run</b> option in the <b>Worklist Options</b> dialog (see chapter 5.4 on page 5-24). This will then be used as the starting basis.

Table 4-5: Columns of the reagent requirements window



*It is possible to print this list and use it as a checklist when preparing the various reagent and control bottles before loading them onto the reagent racks.*

## 4.6.5 System Status

The System status displays a graphical presentation of the work area.

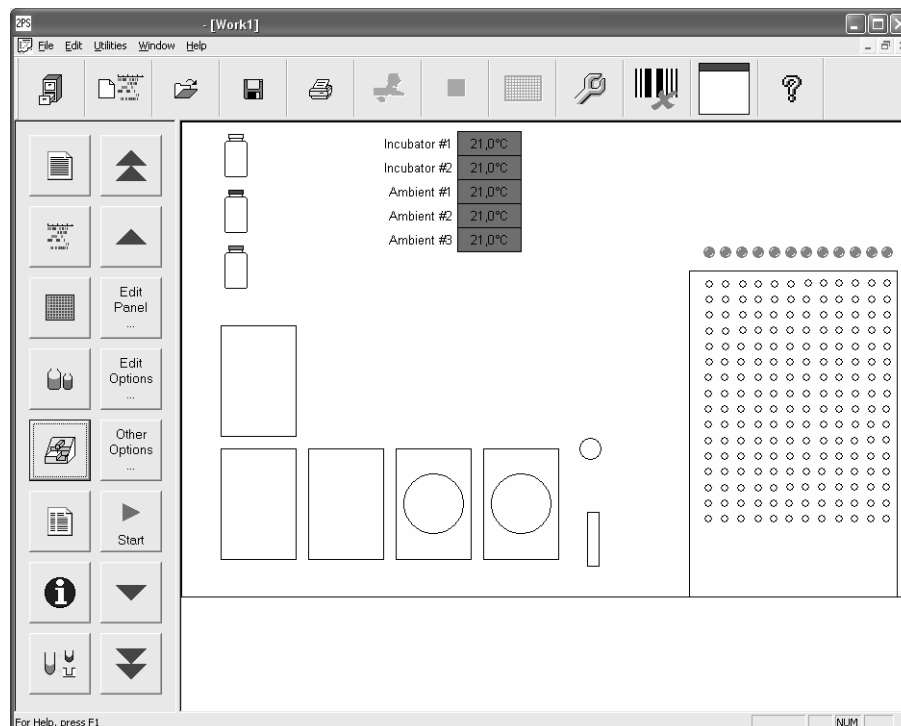


Figure 4-8: Worklist window - system status

- 1 Clean fluid and wash buffers
- 2 3 incubator and 2 ambient positions
- 3 3 tip racks positions
- 4 2 dilution plate positions
- 5 Rack system

This display is useful to check the status of the incubators. If they are functioning correctly, they appear in green; if any problem is detected or before they have reached the correct temperature during preheating, they appear in red. The temperature of each incubator is displayed, as well as the room temperature (below the incubators).

## 4.6.6 Active Event Log

The Active Event Log lists in real time the steps of the run as they are performed. The screen is blank when viewed before the start of the run. The scripting is always done at the top of the list, i.e. the step currently being performed is always at the top of the list while already completed steps are further down.

### Contents:

The wording used in the log file is generally simple and descriptive, making it easy to follow for any operator after minimal use of the **Elisys Duo** system. The only exception to this rule regards the "Dive In/Dive Out" values. These values are included in the log file to allow detailed monitoring of the pipetting/liquid detection system. This monitoring is intended for **Elisys Duo** specialized technicians only. General users can safely rely on existing flags to detect and signal pipetting errors (Clot, NoLiq, InsLiq, see chapter 4.9.2.1 on page 4-62).

If you require assistance in understanding a particular log file, you can easily save it (see below) and mail it to your service engineer.

### Colors:

Different colors are used in the log.

- |              |  |
|--------------|--|
| <b>Black</b> | Used to describe steps that have been correctly performed.                                       |
| <b>Red</b>   | Signals any problem occurring during the run (e.g. incorrect dispense, system paused, errors...) |
| <b>Green</b> | Signals actions taken by the operator to enable the system to resume or continue the run.        |

Example:

```

14:56:36 <System>: Starting worklist.
14:57:21 <System>: 'Pos Ctrl Mono PLUS, 0,6ml' manually assigned to posn.
14:57:21 <System>: 10.2
14:57:21 <System>: 'Neg Ctrl Mono PLUS, 2,3ml' manually assigned to posn. 12.5
14:57:21 <System>: 'Neutr. Mono PLUS, 2,2ml' manually assigned to posn. 12.6
14:57:21 <System>: 'Diluent WB#1 N30 R2, 4,4ml' manually assigned to posn. 12.2
14:57:21 <System>: 'R7a Conj. conc. Mono PLUS, 0,6ml' manually assigned to
14:57:21 <System>: posn. 12.7
14:57:21 <System>: 'Substrate N60 (1:11) R8+R9, 17,0ml' manually assigned to posn. 10.1
14:57:21 <System>: 'Stop Sol. N30 H2SO4 1N R10, 15,0ml' manually assigned to posn. 12.3
14:57:21 <System>: 'R3 Neg Ctrl Mono Ultra, 0,9ml' manually assigned to posn. 10.3
14:57:21 <System>: 'R4 Pos Ctrl Mono Ultra, 0,6ml' manually assigned to posn. 12.8
14:57:21 <System>: 'R7 W1 Spl. Dil. MB, 15,1ml' manually assigned to posn. 12.1
14:57:21 <System>: 'Conj. Mono Ultra, 7,2ml' manually assigned to posn.
14:57:21 <System>: 12.4
14:57:45 <System>: System cover opened.
14:57:54 <System>: System cover closed.
15:01:55 Plate 1: Putting into Ambient 1 at Ambient (26,0°C).
15:02:07 Plate 2: Starting to pipette 'Dispense Positive Control :'.
15:05:39 Plate 2: Finished pipetting 'Dispense Positive Control :'.
15:05:39 Plate 2: Starting to pipette 'Dispense Negative Control :'.
15:06:17 Plate 2: Finished pipetting 'Dispense Negative Control :'.
15:06:21 Plate 2: Reading at 492nm*.
15:07:50 Plate 2: Dispensing 50ul of Neutr. Mono PLUS.
15:08:05 Plate 2: Shaking at 20Hz/0.5mm for 59 seconds.
15:09:09 Plate 2: Reading at 492nm*.
15:09:57 Plate 2: Putting into Incubator 2 at 40,0°C (39,9°C).
15:12:33 Plate 3: Starting to pipette 'Dispense Negative Control :'.
15:13:38 Plate 3: Finished pipetting 'Dispense Negative Control :'.
15:13:38 Plate 3: Starting to pipette 'Dispense Positive Control :'.
15:13:52 Plate 3: Finished pipetting 'Dispense Positive Control :'.
15:13:52 Plate 3: Starting to pipette 'Dispense Samples :'.
...

```

Figure 4-9: Example of an active event log



*Backwards line-wrap. Generally, each operation or user intervention starts on a new line. When the line is too long, it wraps automatically. Note, however that when the log file is "active" (during the actual run), the scripting is done from bottom to top, so that the end of a line will be above the beginning of the line instead of below. In a saved log file on the contrary, the correct line-wrap order (with the end of the line below) is restored.*

#### Use:

The active event log is an important document. It can:

- Be followed while the run is being processed so that the operator can act rapidly to correct any malfunction of the system.
- Be used, after the run is over, to check whether all steps have been properly performed. If, for example, some results are flagged, the active event log enables the user to understand why this is so.
- Be printed.
- Be used at a later date to check how the run was processed.

#### 4.6.6.1 Open a formerly saved Event log File

Event log files are automatically saved by the system. By default, they are saved in the C:\...\Log Files directory. They have a (\*.log) extension and the file name corresponds to the date on which the run(s) was (were) performed:

e.g. "20080315.log" (YYYYMMDD)



*The logs of all the test runs performed on the same day are aggregated in the same log file. Access to the event log file of the current day is restricted. It can only be viewed from the Worklist window. It cannot be opened through the File > Open menu item as indicated below.*

### Open an event log file:



1. Click on the **Open** button.
2. Click on the **Event Log Files** button (see chapter 3.3.1 on page 3-11).
3. Click on the corresponding event log file (see chapter 3.3 on page 3-11).

When the log file is created, the scripting is done in a way that the current step is always at the top while earlier steps are further down. But when you open a formerly saved event log, the daily chronological order is rearranged from start-up to shut-down.

### Event Log Filter

The purpose of the event log filter is to allow the user to find in the log file all the lines related to one specific worklist, one specific plate or even one specific sample.

The event log filter is available only if you open a formerly saved event log. It is not available from the Worklist window or when the run is being processed.

To open the **Event Log Filter** dialog:

1. Open an event log file as described above.
2. Click on the **View > Filter** button.

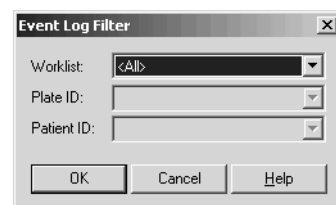


Figure 4-10: Event Log Filter dialog

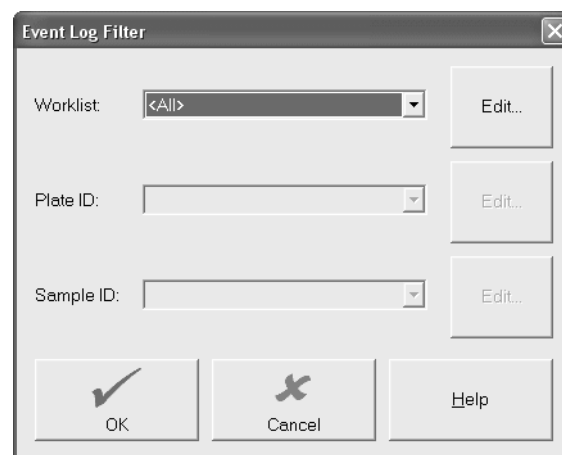


Figure 4-11: Event Log Filter dialog

3. Select a **Worklist**.
4. Select a **Plate ID** (if wished).
5. Select a **Patient ID** (if wished).
6. Click on the **OK** button.

### Event log in (\*.txt) format

Each time a log file is created in (\*.log) format, an identical file is created with a (\*.txt) format with the same filename and in the same directory (e.g.

"20060228.log" => "20060228.txt"). The (\*.txt) file can be viewed with any text editor.

---



*The (\*.txt) version of the log may be changed, even inadvertently. As a result, if you need to send a log file back to your service engineer for troubleshooting or expertise, always send a copy of the actual (\*.log) file rather than the (\*.txt) version.*

---

## 4.6.7 Job List

Selecting Job List shows a reminder of which test(s) are to be performed for which Patient IDs.

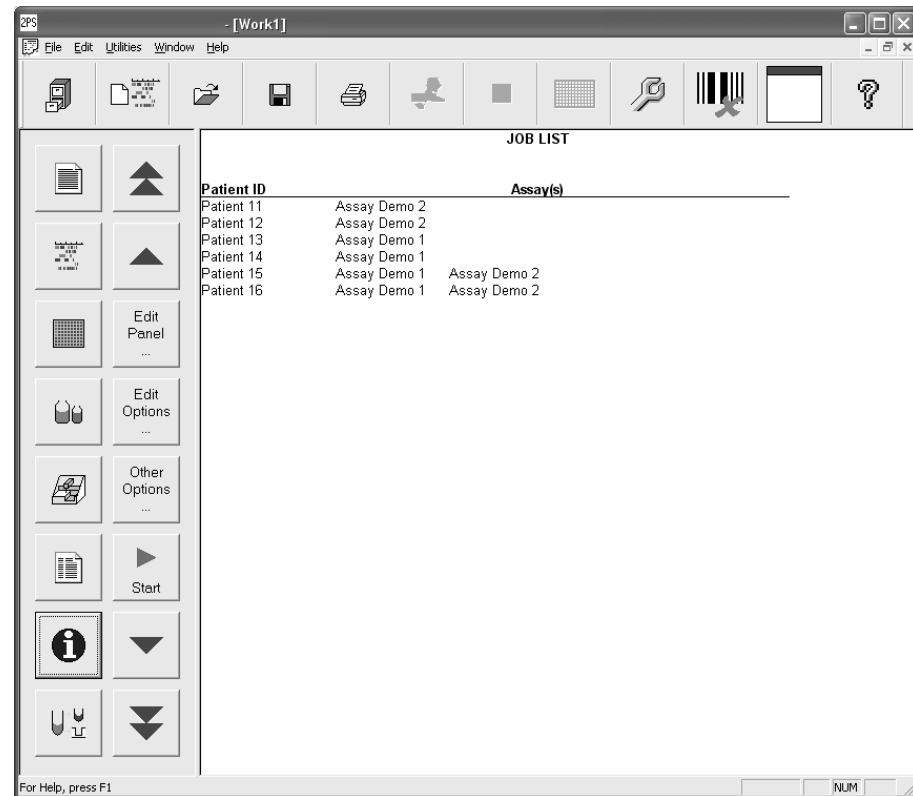


Figure 4-12: Worklist window - job list

## 4.6.8 Sample Archiving Information

Not used.

## 4.7 Start Worklist

If the loaded worklist is error-free, the **Start** button in the worklist window is enabled (appears in green instead of gray). If you click this button, the system prompts you to load the instrument with the required resources (samples, reagents, dilution plates, tip racks, wash buffer, clean fluid...) and opens the **Load** dialog box. Test plates are loaded at a later stage.

The loading process on the **Elisys Duo** system includes three stages:

- The actual (physical) loading of reagents, racks and accessories in the instrument.
- The allocation of these resources in the software.
- The loading of the test plates.

The purpose of the allocation process is to enable the software to track whether each sample, each reagent and each of the other required resources has been loaded, and where it has been placed in the instrument.

When using bar coded components, part of the allocation process is done automatically since the system can then identify each component and monitor its location through the bar code.

For items that are not bar coded, the allocation process is done on the screen in the **Load** dialog (for samples, reagents, dilution plates, and tip racks).

For those elements that have a set location on the instrument (wash buffer, system liquid) the system is able to monitor directly through other devices (e.g. sensors) which quantity is available on the instrument and if more is required for the current worklist, this is displayed in the **Load** dialog. For those elements, no allocation process as such is necessary but they should be loaded on the instrument in strict accordance with what is displayed in the **Load** dialog.

### Procedures



1. Click on the **Reagent requirements** button to note the required wash buffer and clean fluid volume (see chapter 4.6.4 on page 4-20).  
If necessary fill the wash buffer and clean fluid bottles.



2. Click on the **Start** button in the worklist window to start the worklist (see chapter 4.6 on page 4-14).  
The **Elisys Duo** software shows the **Load** dialog (see chapter 4.7.1 on page 4-30).
  - Usually, all samples must be loaded and assigned at this point of time. If, however, you did make supplements during the generation of the worklist, those samples must still be assigned (see chapter 4.7.2 on page 4-34).
  - Load all required reagents (see chapter 4.7.3 on page 4-36). Please observe the hints about unstable reagents (see chapter 4.7.4 on page 4-39).
  - Load all required dilution plates (see chapter 4.7.5 on page 4-41).
  - Load all required disposable tips (see chapter 4.7.6 on page 4-42).
  - Fill wash buffer and clean fluid bottles (see chapter 4.7.7 on page 4-45).
  - Fill system liquid container, if necessary (see chapter 4.7.8 on page 4-46).
3. Click on the **OK** button to confirm the **Load** dialog.



4. Load all required test plates (see chapter 4.7.9 on page 4-46).  
After the last plate, the worklist will be started automatically (see chapter 4.8 on page 4-49).

4.7.1 Load Dialog

The Load dialog illustrates the top level of the instrument (work area):

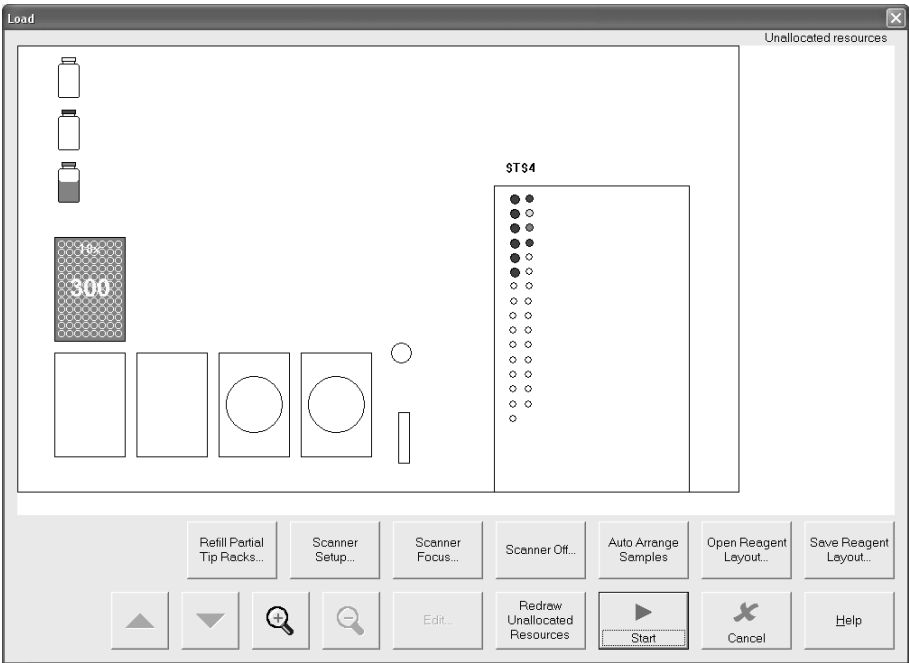






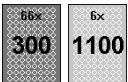




Figure 4-13: Load dialog

Function	Symbol	Description
Auto Arrange Samples		Click this button to allocate all samples in the <b>Unallocated resources</b> column in ascending order on the sample racks (from right to left) (see chapter 4.7.2.2 on page 4-34 on when to use this button).
Clean fluid and wash buffers		The clean fluid and wash buffers symbols indicate which type of clean fluid and wash buffers is required in which bottle (colour-coded lids). By clicking on the corresponding symbol, the type of clean fluid and wash buffers is displayed.
Dilution plate		The dilution plate symbol indicates which type and how many dilution plates you need. If required, you can arrange the dilution plates in another way than suggested (see chapter 4.7.5 on page 4-41).
Edit		Allows you to use already used reagents. After clicking on a reagent and then on the <b>Edit</b> button the <b>Reagent Properties</b> dialog is opened. Enter the remaining liquid in percent.
Free position		Free position for dilution plates or large bottles.
Free position		Free position for tip racks.
Open Reagent Layout		With this function, you can load the positions for reagents saved earlier. This makes the manual assignment obsolete. After clicking on the function, the <b>Open</b> dialog is opened (see chapter 3.3 on page 3-11). <b>Warning: The system won't check opened reagent layouts. Make sure that positions are correct!</b> See chapter 5.5.2.1 on page 5-33 for further information.
Reagents and samples in racks		In the sector rack system, all racks are displayed which have already been loaded. The individual reagents or samples can be assigned to this rack positions. Click on the relevant symbol to get more information on it or the rearrange it. See chapter 2.2.4.1 on page 2-13 for rack indication.
Redraw Unallocated Resources		If reagents or samples are pushed into the sector <b>Unallocated Resources</b> again, it can happen that they are laid on top of each other. With the function <b>Redraw Unallocated Resources</b> , you can have the sector <b>Unallocated Resources</b> rearranged.

Function	Symbol	Description
Refill Partial Tip Racks		Allows you to refill used 300 µl or 1100 µl disposable tip racks.
Save Reagent Layout		With this function, you can save the selected positions for the reagents and re-use them later for a similar test. After clicking on the function, the <b>Save</b> dialog is opened (see chapter 3.4 on page 3-14). See chapter 5.5.2.1 on page 5-33 for further information.
Scanner Focus		Allows to choose the track where the system will accept the next rack. Click on the desired track in the <b>Select a Track</b> dialog. <b>Note:</b> Double lane racks can only be inserted in every 2 <sup>nd</sup> track (the software will reject rack otherwise). <b>See warnings below.</b>
Scanner Off		Switches the bar code scanner off. <b>See warnings below.</b>
Scanner Setup		Opens the <b>Scanner Configuration</b> dialog and you can view and edit the scanner parameters or the rack types and positions (see chapter 5.5.2.2 on page 5-34 on when to use this button).
Start		Closes the dialog when all required resources (samples, reagents, dilution plates, tip racks, wash buffer/clean fluid and system liquid) are properly loaded and allocated and starts the test plate loading procedure (see chapter 4.7.9 on page 4-46).
Tip rack		The tip rack symbols indicate which tip size and how many tips are required. If required, the tip racks can be arranged in another way than suggested (see chapter 4.7.6 on page 4-42). <b>Note:</b> If more tips are required than can be loaded, the missing tips must be reloaded at a later time. The <b>Elisys Duo</b> software indicates the relevant point of time (see chapter 4.6.2 on page 4-17).
Unallocated Resources: Reagents and samples		In the area <b>Unallocated Resources</b> , all reagents and samples required for the test run but have not yet been assigned or loaded are displayed. By clicking on the relevant symbol, you receive more information on it or its assignment.
Zoom In		With this function, you can enlarge the sector rack system and <b>Unallocated Resources</b> . With this enlarged presentation, the assignment of samples and reagents is facilitated.


Function	Symbol	Description
Zoom Out		After clicking on this function, the complete Load dialog is presented.

Table 4-6: Functions of the Load dialog



**Never use the loading bay as storage space! The moving bar code scanner could be damaged or stored objects could be upset.**



**Only load or unload on the indicated lane. Wait for a load/unload message! Wait until the bar code scanner stands idle!**



**Never reach on the right side of the bar code scanner into the loading bay! The bar code scanner could crash into your hand, when it drives back.**

Editing the worklist after the Load dialog is displayed

Sometimes, it is only when the Load dialog is displayed that you realize that some elements of your worklist have not been correctly defined. In this case, you need to go back to the Set-Up Panel dialog and change what you need to change.

**To do this:**

1. Close the Load dialog by clicking the Cancel button (**NOT** the OK button!). This takes you back to the Worklist window.
2. Click on the Edit Panel button to open the Set-Up Panel dialog.
3. Change what you need to change and click on the OK button.
4. Click on the Start button.

A new Load dialog is displayed, reflecting the changes you made.

The same applies for Worklist Options. If you want to change them (e.g. if you have forgotten to specify that you wanted to archive some samples or if you want to work with full tip racks only), repeat the steps described above but click on the Edit Options button.

## 4.7.2 Load Samples

At this stage, the sample racks should already have been loaded in the instrument as described in chapter 4.3 on page 4-5 (it is usually the first thing to do when starting a test run). However, if it has not been done, you can refer to that section and load them now.

- Load Samples and Assign Assays (see chapter 4.3 on page 4-5)
- Allocate Bar Coded Racks and Individual Samples (see chapter 4.7.2.1 on page 4-34)
- Allocate Bar Coded Racks and Non-bar Coded Individual Samples (see chapter 4.7.2.2 on page 4-34)
- Allocate Non-bar Coded Racks and Samples (see chapter 5.5.2.3 on page 5-37)

### 4.7.2.1 Allocate Bar Coded Racks and Individual Samples

If the racks **and** the individual samples were bar coded, they should now appear in the central section of the **Load** dialog as rows of small dots. Moving the mouse pointer over a dot will show the **Patient ID** of each sample. The color of each dot indicates the status of each sample.

- |                |  |
|----------------|--|
| <b>Colored</b> | Indicates samples that have been correctly loaded by the operator and correctly identified by the system through their bar codes. No further allocation is needed. The actual color used depends on what has been specified in the <b>Pipette</b> tab of the <b>System Set-Up</b> dialog (see chapter 7.2.4 on page 7-18). |
| <b>Blank</b>   | Signals either an empty position (i.e. partially full racks) or a sample tube without bar code (or a bar code the system cannot read). Allocate manually if necessary (see chapter 4.7.2.2 on page 4-34).  |
| <b>Black</b>   | Indicates a sample that has been loaded but which is not required for the run, i.e. no assay is assigned to that sample. Either remove the sample from the rack or go back to the <b>Set-Up Panel</b> dialog to check why this is so and correct the assay assignment for this sample.                                     |

For more details on bar code settings, see chapter 7.2.5 on page 7-25.

### 4.7.2.2 Allocate Bar Coded Racks and Non-bar Coded Individual Samples

If the racks were bar coded but not the individual samples, the racks are depicted as empty (rows of blank dots) in the central section of the **Load** dialog while the samples are depicted as **Unallocated** resources. You now need to allocate them either manually or automatically.

To allocate samples manually:

1. Click on the first sample (colored dot) in the **Unallocated** resources area you want to allocate. This will show its code name/ID.
2. Click on the rack position, where the sample is located in the instrument. The sample is moved in the **Load** dialog.
3. Repeat for each sample.



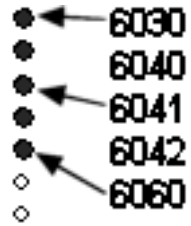
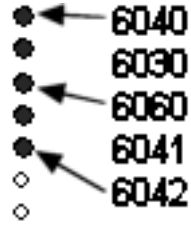
*Make sure that the position to which you allocate a sample on the screen corresponds exactly to the real position of the corresponding sample tube in the*

*rack! This is very important as wrong allocation is equivalent to mixing up samples.*

## Auto Arrange Samples

To allocate samples automatically:

1. Click on the **Auto Arrange Samples** button in the Load dialog. The unallocated samples are then allocated to the available sample racks, from the top down and starting with the first rack on the right. The order in which samples are allocated to the consecutive rack positions (position 1, position 2, etc.) follows the order selected in the **Patient Editor** dialog (Ascending, Descending or None - see chapter 5.2 on page 5-4) as illustrated below.

Order:	Patient Editor:	Sample Rack:
Ascending	6030 6040 6041 6042 6060	
None	6040 6030 6060 6041 6042	



*Automatic allocation is a timesaving option if you have a lot of non-bar coded samples to allocate. It implies that the person who actually places the sample tubes in the racks and the racks in the instrument does it in strict compliance with the order resulting from the automatic allocation.*



*Make sure that the position to which the system or the user allocate a sample on the screen corresponds exactly to the real position of the corresponding sample tube in the rack! This is very important as wrong allocation is equivalent to mixing up samples.*

## 4.7.3 Load Reagents

### 4.7.3.1 Placing the Reagents on the Racks

On the **Elisys Duo** system, there is no need to transfer the kit reagents into any particular container before loading them on the instrument. The **Elisys Duo** reagent racks have been specially designed to accept all Human kit bottles as well as most types of kit bottles, vials or tubes available on the market. The reagents can therefore generally be placed directly in the racks.

There are only a few cases where this is not possible: unstable reagents which have to be prepared separately, kit bottles too large (e.g. 125 ml bottles) or too small for the racks, controls which have to be decanted in haemolysis tubes. These cases are dealt with in chapter 4.7.3 on page 4-36 and chapter 4.7.4 on page 4-39.

For more information on Human rack types, see chapter 2.2.4 on page 2-12.



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*Do not refrigerate reagent racks! Because they are made of metal, excessive cooling of the racks could influence the temperature of the reagents and of the work area inside the instrument.*

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*Use only exact modelling of tubes and bottles to ensure correct tracking.*

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Using the reagent requirements checklist (see chapter 4.6.4 on page 4-20), check that you have fitted all the required reagents on the racks. If you need a reminder of where you placed each reagent/control, you can copy and fill in the rack layout forms.

When opening the reagent bottles, be careful not to mix the bottle caps as these may be needed again after the run and should not be exchanged from one bottle to another.

### 4.7.3.2 Loading the Racks on the Instrument



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***Never use the loading bay as storage space! The moving bar code scanner could be damaged or stored objects could be upset.***

---



---

***Only load or unload on the indicated lane. Wait for a load/unload message! Wait until the bar code scanner stands idle!***

---



---

***Never reach on the right side of the bar code scanner into the loading bay! The bar code scanner could crash into your hand, when it drives back.***

---



---

*Do not touch the bar code scanner while loading a rack!*

---





*Do always push in the racks into the rack system with the handle or pull it out again with the handle.*



*Insert the racks carefully to avoid tipping over and spilling of bottles or tubes.*



*In one rack, only tubes of the same type may be used to avoid problems during the aspiration of liquids. The tube type must be approved for the relevant rack.*



*Never load more than one rack at the same time! For proper bar code identification the racks must be loaded one after the other, as indicated by the LEDs.*

1. Once you have fitted all the required reagents on the racks.
2. Insert the first rack on the lane that is marked by a LED. Place the rack in front of the lane and then push evenly up to the limit stop (with the tappet in the contact opening on the rear panel). A reagent rack occupying 2 or 3 tracks must be inserted so that the contact tappet is opposite the lit up LED. The bar code labels (if any) must face right towards the bar code reader.
3. The LED goes off and moves to the next position that can be loaded. A graphical representation of the correctly inserted rack appears in the Load dialog on the screen.
4. Insert the next reagent racks (if any) as described.

#### **4.7.3.3 Allocate Bar Coded Racks and Bar Coded Reagent Containers**

If both the racks AND the individual reagent containers, vials or bottles were bar coded and were correctly inserted, the racks and the reagent containers should now be displayed on the screen in the rack system area of the Load dialog:

- The reagents that are required for the run and have been correctly loaded and identified (through their bar codes) are automatically allocated and appear in the racks as larger or smaller colored dots (a different colour is used for each reagent) with a cross.
- Loaded reagents that are on the instrument and have already been identified through their bar codes (or otherwise allocated) but are not needed for the current worklist are presented in black.

For more details on bar code settings, see chapter 5.3.3 on page 5-19.

#### **4.7.3.4 Allocate Non-bar Coded Individual Reagent Containers**

Unlike samples, reagent containers usually have bar codes. Reagent bar code stickers can also be ordered separately.

However, it can happen that a bar code is missing, damaged or illegible. When a container with a missing or damaged bar code is loaded and the system is not able to identify the reagent, the corresponding rack position is displayed as empty (larger

blank dot) and the required reagent remains depicted in the **Unallocated resources** area of the **Load** dialog. It has to be manually allocated.

**Manual allocation of reagents:**

1. In the **Unallocated resources** area, identify the reagent you want to allocate by clicking on it. This shows its code name/ID.
2. Click on that reagent and then click on the desired location (corresponding blank position in the reagent racks in the system rack area of the **Load** dialog).
3. Repeat for each unallocated reagent.



---

*The user has to make sure that the manually allocated positions correspond to the actual placement on the reagent rack. Manually allocated reagents are not crossed. In the log file, manually allocated reagents can be tracked as such.*

---

The **Auto Arrange** function (automatic allocation of non-bar coded resources) is not available for reagents (only for samples, see chapter 4.7.2.2 on page 4-34). For reagents, a similar function is provided by the **Save Reagent Layout/Open Reagent Layout** buttons (see chapter 5.5.2.1 on page 5-33).

#### **4.7.3.5 Allocate "Blind" Reagent Positions**

Manual allocation is also necessary when reagent bottles (whether bar coded or not) are placed in any of the dilution plate positions (with intended adapter). These positions cannot be scanned for bar codes. As a general rule, avoid using these positions if other positions of the same size are still available.

#### **4.7.3.6 Allocate Non-bar Coded Reagent Racks**

If the reagent racks do not have bar codes, you can identify them manually as described for non-bar coded sample racks (see chapter 5.5.2.3 on page 5-37).

Replacement bar code labels for reagent racks can be ordered.

#### **4.7.3.7 Identical Reagent in Two Separate Bottles**

In some cases, two separate bottles of the same reagent are required for the same assay. If this has been taken into account in the assay definition and when entering the reagent in the reagent database (see "Assay Programming Manual" - "Allow changing of bottles during a dispense"), the pipettor will automatically switch from one bottle to the other during the run avoiding having to pause the run, exchange bottles, etc.

To make sure this switch is correctly performed:

- Make sure to fill each bottle with the appropriate volume (as specified in the **Reagent Requirements** list, see chapter 4.6.4 on page 4-20). At any rate, the total volume should equal the total volume specified in the list.
- Load both bottles on the rack before the start of the run.
- If the bottles are non-bar coded, allocate them manually in the **Load** dialog to the respective rack locations (if the bottles are bar coded, they should already be allocated when the **Load** dialog is displayed).

## 4.7.4 Load Unstable Reagents

Some unstable reagents have to be prepared separately and loaded on the instrument only after the test run has begun.

### Preparing the Reagent

The preparation procedure depends on the reagent required. Please refer to the appropriate documentation.

However, the following recommendations apply to all separately prepared reagents:

- Do not fill the bottle above the shoulder level.
- If a bottle for this preparation is not included in the kit but a specific bottle type is recommended, always use the recommended type.
- Follow strictly the recommendations on reusing the bottles. Even if reusing a bottle is allowed, never use the same bottle for different reagents and follow strictly the recommended maintenance procedure.
- Attach a bar code label to the bottle. Using non-bar coded bottles for unstable reagents is not recommended (see chapter 9.2.2.1 on page 9-18).

### Loading the Reagent

If an unstable reagent is required for a test, it will be listed in the **Reagent requirements** list (see chapter 4.6.4 on page 4-20).

When the **Load** dialog opens for the first time, load all required reagents **except** the unstable reagent. Allocate the unstable reagent manually, click on it in the **Unallocated resources** area and then click on the rack position where you will later load it.

Because the properties of this reagent have been included in the reagent database (see "Assay Programming Manual"), the system knows that this reagent requires a preparation time. Before the reagent is actually needed, the system prompts the operator with an acoustic signal and a message on the screen to prepare and load the reagent ("Prepare [name of reagent] and load in xxx minutes").



*The time span specified in this message to prepare the reagent is a theoretical time span determined by the system from the data included in the reagent database (see "Assay Programming Manual"). It is recommended that you do not wait until this message is displayed to prepare the reagent (i.e. you should anticipate its preparation).*

1. Click on the **OK** button to close this message. The processing of the worklist continues and when the indicated time span is over, the **Load** dialog is displayed again with an additional message "Please load the requested items as soon as possible as the system is paused".
2. Remove the reagent rack in which you initially allocated the unstable reagent.
3. Place the reagent bottle in the position indicated in the **Load** dialog.
4. Re-insert the rack and close the door of the sample and reagent unit.
5. Then click on the **OK** button.

The time span available to actually load the reagent has been defined in the **Worklist Options** dialog (see chapter 5.4 on page 5-24). Recommended time is 180 seconds (3 minutes). If the reagent has not been loaded within that time, the system will either:

- abort the plate for which this reagent is required if this option has been checked in the **Worklist Options** dialog, or

- pause the system until an operator loads the required reagent.



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*Note that in the latter case, the resulting pause can lead to wrong incubation times and - if a washing step is affected - dehydration of wells. In case an unstable reagent is loaded not in time, carefully check the results and the event-log. Excessive incubation times will be flagged automatically, but in doubt discard the results produced when a long pause of the worklist is reported.*

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*Never click on the OK button before loading the reagent! Even if you could do it, the system would not take it into account and would not dispense the reagent.*

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### Troubleshooting

- Non-Bar coded unstable Reagents (see chapter 9.2.2.1 on page 9-18)

## 4.7.5 Load Dilution Plates

Types of dilution plates:

Various types of dilution plates may be used on the **Elisys Duo** system: flat bottom plates, round bottom plates or deep well dilution plates.

The specifications of each plate type are stored in a coordinate file. Plate coordinate files have a (\*.mpc) extension. They cannot be opened directly.

A default dilution plate type is selected at system level in the **Pipette** tab of the **System Set-up** dialog (**Dilution Plates** field, see chapter 7.2.4 on page 7-18).

When loading the required resources for your worklist, you can check which type of dilution plate is required by clicking on the dilution plate in the **Load** dialog.

If you want to change the type of dilution plate used (for example, if you want to use a deep well dilution plate instead of a flat bottom standard dilution plate), change the default dilution plate type (see chapter 7.2.4 on page 7-18).

### Load Dilution Plates

1. Make sure that the metal base plate(s) are in place.
2. Insert the dilution plate(s), shown in the **Load** dialog, into its correct position(s). Push the dilution plate(s) firmly down so that they lay on the metal base plate(s) completely and evenly.  
Position A1 should be at the rear right.



*To change the default dilution plate type, see chapter 7.2.4 on page 7-18.*



*Use only exact modelling of microplates to ensure correct tracking.*



*Single-use microplates may not be used repeatedly!*



*When loading dilution plates, make sure not to mix pre-dilution plates (for assays which require a pre-dilution step) and archive plates (for sample archiving). In the **Load** dialog, these are identified by different colors.*

## 4.7.6 Load Tip Racks

### Tip Types

The pipettor on the **Elisys Duo** system operates with disposable tips. Two different types of tips can be loaded on the instrument:

- 1100 µl tips (long tips)
- 300 µl tips (small tips)

Because the pipettor on the **Elisys Duo** system is also used for liquid level detection, clot detection, etc., the tips have to enable conductivity. Therefore do not replace the recommended tips by other tips with different conductivity properties.

Ordering information for recommended tips is available in chapter 12.1 on page 12-1.

### Tip Rack in the Load dialog

The Load dialog shows the number of tips of each size required to perform the current worklist.

The colors in which the tip racks are displayed vary not only according to the required tip size but also according to whether racks are already available on the instrument.

Color	Tip size	Description
Grey	1100 µl	Load a full new tip rack with 1100 µl tips.
Red	1100 µl	An incomplete tip rack is already loaded. The number of tips that are still available is taken into account by the software.
Green	300 µl	Load a full new tip rack with 300 µl tips.
Red	300 µl	An incomplete tip rack is already loaded. The number of tips that are still available is taken into account by the software.

Table 4-7: Tip racks in the Load dialog

### Load Tip Racks



*Single-use tips may not be used repeatedly!*

1. Insert the tip rack(s), shown in the Load dialog, into its correct position(s). Push the dilution plate(s) firmly down so that they lay on the floor completely and evenly.  
Place the tip rack into the holding device of the instrument, so that the pin sits in the groove of the tip rack (right rear).



*Always observe the position of the tip racks defined in the Load dialog! Using a short tip instead of a long one may cause splashing and contamination. Using a long tip instead of a short one may cause the pipettor to crash and be damaged. Note that the **Elisys Duo** system can be configured to perform an automatic tip size check (see chapter 4.8.1.4 on page 4-52).*

#### 4.7.6.1 Tip Management Options

The Elisis Duo system offers several tip management options depending on whether you want to be able to reuse partial tip racks and whether you are prepared to reload tips during a run or want the system to operate unattended as much as possible.

##### Use only full Tip Racks

If you prefer starting a run with only full tip racks:

- Deselect in the **Panel Options** the **Re-use partial disposable tip racks** checkbox (see chapter 5.4 on page 5-24).

Worklist options settings are retained until they are edited again. This means that you do not have to do this before each run (the option continues to apply to all later runs unless you decide to change it).

When you actually load the tip racks on the instrument, make sure to unload all partially used tip racks and load only full tip racks (in the **Load** dialog, only gray and green tip racks should be displayed).

##### Reuse partially used Tip Racks

If you prefer starting a run with partially used tip racks (i.e. the tips left over from the previous runs):

- Select in the **Panel Options** the **Re-use partial disposable tip racks** checkbox (see chapter 5.4 on page 5-24).

This is possible because, while it operates, the system monitors the number of tips used. At the end of a run, it knows how many tips of each size are still available. If the **Re-use partial disposable tip racks** option is selected, when the system calculates the number of tips required to perform the next worklist, it takes into account the number of tips still available on the instrument. In the **Load** dialog, partially used tips racks are displayed in red.

##### Reload Tip Racks during a run

If you want to try and avoid having to reload tips during the run, it is recommended to work only with full tip racks (i.e. to deselect the **Re-use partial disposable tip racks** checkbox (see chapter 5.4 on page 5-24)). However, even if you started the run with only full tip racks, it may still be required to reload tips during the run if you are processing "heavy" worklists (e.g. with several tests, many samples, a pre-dilution and/or a sample archiving step).

If tip reloading is going to be required in the course of a run:

- At the bottom of the **Schedule** display (see chapter 4.6.2 on page 4-17), the system displays the following indication: "Operator intervention required in X minutes".
- A message on the screen and an acoustic signal warns you when it is time to get ready to reload.



- The **Load Additional Tips** button is then enabled.
- Click on the **Load Additional Tips** button and reload the tips as described in (see chapter 4.7.6 on page 4-42).

##### Abort Plate if small Tips run out

The **Panel Options** dialog also includes a **Abort plate if 300 l tips run out** option checkbox. This option is useful when the system operates mostly unattended (e.g. at night).

- Select in the **Panel Options** the **Abort plate if 300 l tips run out option** checkbox (see chapter 5.4 on page 5-24) to use this function.

In most cases, if you initially loaded the tips as required in the **Load** dialog, the need for reloading will arise only for the last plate of a worklist. If this option is not selected, the system then prompts you to reload and pauses the pipetting until new tips have been reloaded, with the risk of blocking the whole run for a long time if no operator is there to load the new tips.

With this option, you can decide that if such a situation arises, only the last plate is aborted but the processing of the run continues normally for those plates that have already been dispensed.

This option is available for small tips (300 µl) only as these are the tips used for sample dispensing and likely to run out. Generally, the rest of the processing (e.g. reagent dispensing using large tips - 1000 µl) can continue unaffected. Note that it is not possible for the system to switch to large tips if it runs out of small tips as this would alter the pipetting accuracy negatively.



## 4.7.7 Fill Wash Buffer and Clean Fluid

### Instrument

The wash buffer and clean fluid bottles are located on the left side of the instrument.

- Two 2-liter bottles can be used for various buffers.
- Another position (1 liter bottle) is reserved for the clean fluid used to clean the washer head.

The connection fitting consists of 3 color-coded lines (cap, tubing, filter) allowing a better identification of each one as well as level sensor per bottle.

### Load Dialog

In the Load dialog, when you have loaded a correct worklist and clicked on the Start button, the required wash buffer(s) and clean fluid are displayed in the respective containers (see chapter 4.7.1 on page 4-30). The containers are identified through colored screw caps.

Under default settings, the clean fluid bottle is the first bottle on the left. For wash buffers, the system determines what buffer should be put in each bottle. Click on each bottle to see the name of its corresponding buffer.

If, for some reason, you do not wish to fill a buffer in the bottle specified by the system (e.g. if the blue-capped bottle is damaged) you can click on the desired buffer and allocate it to the desired bottle. If you want to always use the same bottle for the same type of wash buffer (e.g. blue-capped bottle for wash buffer), you can do so by changing the washer default settings (see chapter 7.2.6 on page 7-29).

In any case, make sure that when you actually fill the bottles, you do it in strict compliance with what it set in the Load dialog.




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*Do not confuse the bottles or liquids!*

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#### To fill in wash buffer/clean fluid:

1. Unscrew the cap of the respective wash buffer bottle. Refill it or replace it with another full wash buffer bottle.
2. Screw the cap back on carefully and watch out for correct seat of level sensor and connections.

### Type of Wash Buffer/Clean Fluid

The type of wash buffer to be used for a test is specified during assay definition (see "Assay Programming Manual"). The properties of each wash buffer are stored in the reagent database and can (in some cases) be edited.

Deionised water is used as clean fluid.

### Quantity of wash buffer/clean fluid

The Reagent requirements list (see chapter 4.6.4 on page 4-20) lets you know the quantity of wash buffer and clean fluid required for the respective worklist. If you have filled in the correct quantities, then no refill should be needed during the run.

The system automatically monitors the quantity of wash buffer left and warns the operator before each run or before each wash cycle, if the quantity still available is not sufficient (see chapter 4.8.1.1 on page 4-50).

### 4.7.8 Fill System Liquid

Normally, system liquid can be filled in as soon as the instrument is installed, as described in chapter 2.1.3 on page 2-4 and chapter 2.2.8.2 on page 2-15. Checking the level of system liquid (and refilling the container if necessary) is also prescribed as part of the daily start-up maintenance routine (see chapter 8.2.1 on page 8-3). If this has been done as prescribed, no additional refilling should be required before each run.

### 4.7.9 Load Test Plates

When all the required resources (samples, reagents, dilution plates, tip racks, wash buffer/clean fluid and system liquid) are properly loaded and allocated, close the Load dialog by clicking on the Start button.

The system automatically moves a plate carrier to the loading position. The Load Plate dialog is displayed. The software uses this dialog box to request the test plates that are needed to perform the current worklist.



*Test plates can only be loaded when this is requested by the software!*



*Use only exact modelling microplates to ensure correct tracking.*



*Single-use microplates may not be used repeatedly!*

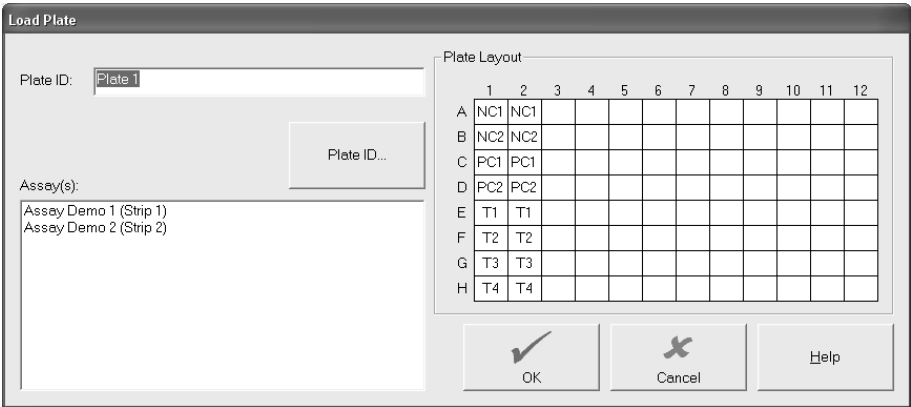


Figure 4-14: Load Plate dialog

Function	Description
Plate ID	Shows the name of the requested plate as defined in the <b>Set-up Panel</b> dialog. If you have not yet defined a plate ID, click on the <b>Plate ID</b> button and enter a plate ID of up to 12 characters.  It is advantageous to add an 8-character "YYMMDDNN" identifier (with YY = year, MM = month, DD = day and NN = "00" for the first plate of the day, "01" for the second plate, etc.) at the end of the plate IDs.  Depending on the system configuration provided by the manufacturer this will be automatically done by the software.
Assay(s)	Shows the assay(s) used on the displayed plate.
Plate Layout	Shows the sample/well allocation on the plate.

Table 4-8: Functions of the Load Plate dialog

Test plates used on the **Elisys Duo** system are 96-well microplates (8 rows of 12) with or without removable strips. The precise type of plate used for a test is specified during assay definition (see "Assay Programming Manual").



*Check that you are using the correct plate corresponding with the assay!*



*If you are using more than one assay per plate check that the strips correspond with the plate layout!*

#### To load the test plates:

1. In the **Load Plate** dialog, the first plate (of the current worklist) is requested for loading. Check the **Plate Layout** displayed in the right-hand side of the dialog.
2. Place the requested test plate correctly onto the plate transport unit before the test plates can be loaded into the instrument. To do so, fit the plate into the frame so that the A1 corner of the plate matches the A1 inscription on the frame (rear right), then push it in, overcoming a slight resistance. Make sure that you do not move the plate carrier. It must remain firmly held by the catch spring of the plate transport.
3. As soon as you have inserted the plate, enter the plate name and then click on the **OK** button. The test plate is pulled in. In order to save time in case **OK** is accidentally clicked before the plate is actually loaded, the software will not close the **Load Plate** dialog in case no opening and closing of the cover for loading a plate has been detected.
4. The test plate is then moved first into the photometer to check that the correct number of strips is present. The plate is then moved into the stacker. Meanwhile the **Load Plate** dialog is closed.
5. The plate transport unit moves the next plate carrier to the load position and the **Load Plate** dialog prompts you to insert the second plate.

6. Repeat the procedure for each requested plate.  
After the last plate, the worklist will be started automatically (see chapter 4.8 on page 4-49).

## 4.8 Processing the Run

Once all the prerequisites steps (load samples, assign assays to samples, define worklist, load required resources, load test plates) have been completed and you have clicked **OK** in the **Load Plate** dialog, the software downloads all the processing information to the instrument and the test run starts.

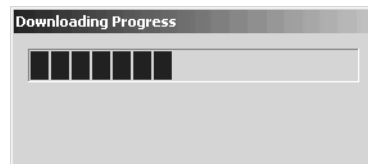


Figure 4-15: Acknowledging Progress dialog

The **Elisys Duo** instrument is locked during a run.

The cover is automatically locked before the processing can start. If the cover is not completely closed the system cannot be locked and the processing cannot start, and the software will ask you to close the cover first.

If the system has been configured so that a selftest is performed before each run (see chapter 5.1 on page 5-1) the cover is locked during this pre-run selftest.

It is possible to disable the automatic cover lock (in the **System Set-up**, see chapter 7.2.1 on page 7-12). This, however, is not recommended and may be done only by supervisors or users who are authorized to change the **System Set-up**. Even if the cover may be opened, opening it will automatically stop the processing (pause the worklist).

The cover will automatically unlock if an error occurs or if the **Stop** button is clicked (see chapter 4.8.5 on page 4-55). It will be locked again when the error is cleared or when the **Resume** button has been clicked.

## 4.8.1 Pre-Run Checks

Before actually processing the assays, the system will perform pre-run checks. The wash buffer / clean fluid volume check is performed automatically. The three other pre-run checks (reagent volume check, sample volume check and tip size check) are optional. They are performed only if the user has requested them by checking the corresponding items in the **Worklist Options** dialog (see chapter 5.4 on page 5-24).

### 4.8.1.1 Wash Buffer/Clean Fluid Volume Check

The level of liquid in the wash buffer/clean fluid bottles is monitored through level sensors. If the level detected in a bottle is not sufficient for the current worklist, the following message is displayed:

"Insufficient volume of 'LIQUID', position POS, for the worklist."

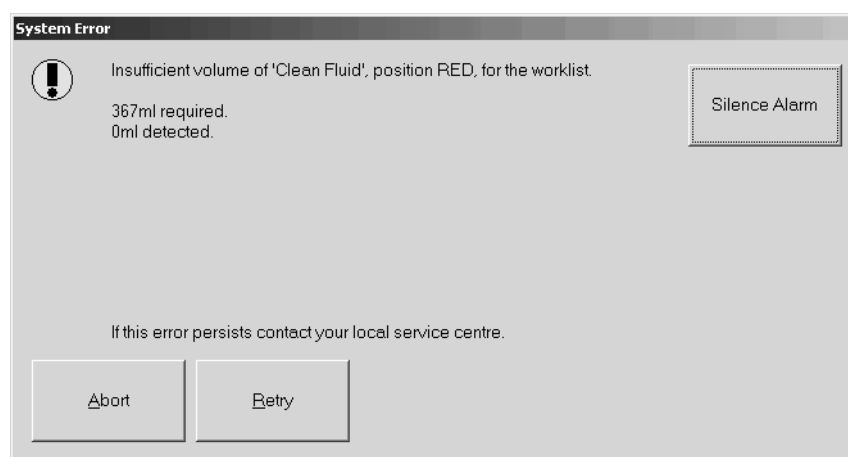


Figure 4-16: Insufficient volume dialog

The message tells you which buffer is required in which bottle (color indication).

#### Refill:

1. Refill the liquid bottle (see chapter 4.7.7 on page 4-45).
2. Click on the **R**etry button. The system rechecks the volume and, if satisfactory, goes on to check the volume of the next wash buffer.



*Only applicable if washer bottles with advanced level sensors installed. With standard washer bottles, the system will only raise an error message if the remaining volume is below the minimum volume (dead volume).*

### 4.8.1.2 Reagent Volume Check

The systems checks that all the reagents needed for the current worklist have been loaded in sufficient quantity. To do this, the pipettor actually checks every reagent bottle until the tip touches the surface of the reagent and the system calculates the volume that is available.

If the system finds that the volume of a reagent is lower than what is required for the current worklist, the error message (see figure 4-16: on page 4-50) is displayed.

The message shows the name and the location of the reagent to be restocked.

**To refill the respective reagent or to replace it by a new bottle:**

1. Click on the **Refill Bottle** button:
2. Move out the respective reagent rack.  
The **Load** dialog shows you where it should be placed.
3. Refill the respective reagent bottle or replace the bottle.
4. Insert the rack again. If the reagent was allocated manually, the position in the rack has to be allocated again.
5. Click on the **OK** button.  
The software will check that all of the bar coded reagents in that rack are still in their correct positions. If not, an error message will be displayed and you will be given the opportunity to reload the rack or to continue anyway. If you chooses to continue anyway then this will be logged in the event log and all wells that will subsequently use one of the incorrect reagents will be flagged with the **RgtRem** flag. When all of the bar codes have been verified the rack LED will be turned off. The system will check the volume of the next reagent.

#### **If the reagent cannot be supplied:**

In this case there are two possibilities:

- Click on the **Abort Worklist** button. This will abort any further volume check but it will also abort whole the test run.
- Click on the **Continue** button. This skips the volume check for this specific reagent only and continues with the reagent check for the next one. The insufficient volume is logged. With this option, you may decide to start the run and load the missing reagent at a later stage. If you do not refill the corresponding reagent, then some wells will not have reagent dispensed.



*The reagent volume check is a good option if you intend to use the **Elisys Duo** as a "walk away" system (e.g. at night). However, it takes time and uses several tips (one per reagent bottle or control vial).*

#### **Delayed volume check for unstable reagents:**

Unstable reagents have to be prepared and loaded just before use, i.e. while the run is already being processed (see chapter 4.7.4 on page 4-39). As a consequence, they cannot be included in the pre-run reagent volume check. If the reagent volume check option has been selected for a run including unstable reagents, the system will perform the pre-run check for all other reagents but will also perform a volume check on the unstable reagents later, once these have been loaded.

If the volume detected is not sufficient, the available options are:

- **Continue** to continue the worklist and flag the corresponding results.
- **Refill Bottle** to load additional reagent and allow the system to continue the worklist without flagging the results
- **Abort Plate(s)** to abort all plates that require this particular unstable reagent.

#### **4.8.1.3 Sample Volume Check**

The sample volume check is very similar to the reagent volume check.

Obviously (depending on the number of samples you intend to test), it is likely to take even longer than the reagent volume check and use even more tips (one per sample tube). It is therefore recommended only as a response to specific sample volume problems.

#### 4.8.1.4 Tip Size Check

If the **Verify disposable tip racks** option in the **Worklist Options** dialog (see chapter 5.4 on page 5-24) has been checked, the system automatically checks the size of the first tip of each rack to make sure the racks have been loaded in the correct locations.

The consequence of this verification depends on whether the tip checked corresponded (or not) to the type of tip the software expected to find on that rack (as displayed in the **Load** dialog).

Expected tip size	Detected tip size	Consequence
300 µl	300 µl	The pipettor uses this tip normally for the pipetting step.
300 µl	1100 µl	The pipettor ejects the tip. The system displays an error message telling the user to go back to the <b>Load</b> dialog, check in which order the tip racks should be loaded and change them accordingly in the instrument. When the user closes the <b>Load</b> dialog, the system checks the tip size once more.
1100 µl	1100 µl	The pipettor ejects the tip. It will use the next tip on the same rack to perform the next pipetting step.
1100 µl	300 µl	The pipettor ejects the tip. The system displays an error message telling the user to go back to the <b>Load</b> dialog, check in which order the tip racks should be loaded and change them accordingly in the instrument. When the user closes the <b>Load</b> dialog, the system checks the tip size once more.

Table 4-9: Tip size detection

Long tips have to be systematically discarded after a check because the checking process is a mechanical process, which means that long tips come in contact with the stopper (but not small tips).

The system keeps track of all tips retained or discarded during this process when calculating the number of tips left in the partially used racks.

#### To change incorrectly loaded tips:

1. Remove the tip rack with the wrong-size tips and replace it with a correct tip rack.



## 4.8.2 Steps of a Typical Test Run

The different steps (also their duration and sequence) that will be performed by the instrument during a run depend on which assays are to be tested in the run.

In a typical test run:

- The test plate will be transported to the pipetting position.
- The pipettor will aspirate the samples from the tubes (in the order defined in the complete **Patient Editor**, see chapter 5.2 on page 5-4) and the controls from their respective bottles. It will then dispense them into the test plate.
- The plate will be transported to the photometer for dispense verification.
- The plate will go through an incubation period.
- The plate will be transported to the wash unit for washing.
- The pipettor will dispense the reagent.
- The plate will be transported to the photometer for dispense verification.
- The plate will go through a second incubation period and a second wash.
- The pipettor will dispense the substrate.
- The plate will go through a third incubation period.
- The pipettor will dispense the stop solution.
- The plate will be transported back to the photometer for the final read.

In some cases (depending on the assay):

- A pre-dilution step will be performed at the beginning. This pre-dilution can take place either directly in the test plates or in dilution plates.
- Shaking steps will also be included. The test plates can be shaken either when they are in the heated incubators or on the plate transport unit.

When several assays are combined in the same worklist, the system does not process one plate after the other but optimizes the process so as to shorten the total processing time (see chapter 4.6.2 on page 4-17).

On partial processing (i.e. processing only some steps of an assay, see "Assay Programming Manual").

### 4.8.3 What You Can Do While the Run is Being Processed

The **Elisys Duo** system has been designed as a "walk-away" system, which means that if everything has been correctly planned it can operate unattended.

Three exceptions, however, require the intervention of an operator during the run:

- When tips need to be reloaded.
- When an unstable reagent needs to be loaded.
- When a system error or a pipetting error occurs.

If you wish to monitor the run process:

- Click on the **Schedule** button in the Worklist window to follow the run on the **Schedule** screen (see chapter 4.6.2 on page 4-17).
- Click on the **Active event log** button to check the active event log (see chapter 4.6.6 on page 4-23) to see if the different steps are correctly executed.



---

*While the run is being processed **DO NOT** interfere in any way with the process unless it is requested by the software. For the emergency stop procedure, see chapter 4.8.7 on page 4-57. On removing sample or reagent racks before the end of a run, see chapter 4.10.2 on page 4-69 and chapter 4.10.3 on page 4-69. On reloading samples or test plates, refer to chapter 5.6 on page 5-44.*

---

#### Reloading Tips

If tip reloading is going to be required in the course of a worklist, see chapter 4.7.6.1 on page 4-43

#### Loading an unstable Reagent

If a specific reagent needs to be prepared after the run has been started, the software will warn you in advance and direct you to load it as described in chapter 4.7.4 on page 4-39.

## 4.8.4 System/Pipetting Errors

The system automatically pauses the run when system errors are detected. Check the error message list in chapter 9.1 on page 9-1.

Depending on the kind of error detected the system will either display a specific error message, describing the problem, or open the **System Paused** dialog (see chapter 4.8.5 on page 4-55) and describe the problem detected in the status bar.

When specific pipetting errors occur, the system can also pause the run and request the intervention of an operator.

## 4.8.5 The System Paused Dialog

This dialog is displayed either when a system error occurs (see chapter 4.8.4 on page 4-55) or if you click on the **Stop** button in the toolbar (see chapter 3.1.3 on page 3-5).

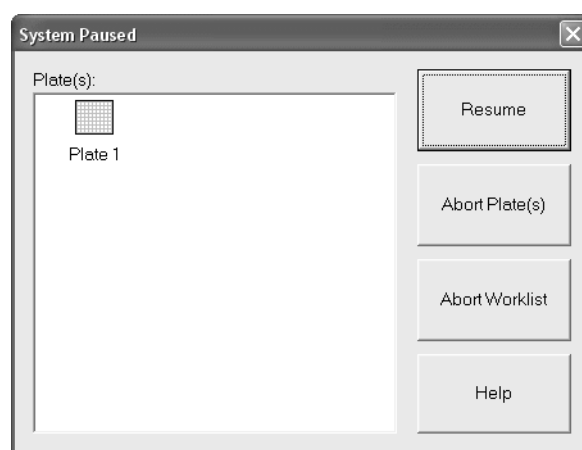


Figure 4-17: System Paused dialog

Function	Description
Plate(s)	Shows the plates that have yet to be processed. Plates that have not yet been completely processed are displayed as well.
Resume	Continue the run.
Abort Plate(s)	In the plates list, select the plate(s) that you do not want to process any more. Then click on this button to delete them from the worklist. You can then continue the run with the remaining plates only.
Abort Worklist	The run is over. None of the plates listed in the Plates list will be processed any more.

Table 4-10: Functions of the System Paused dialog



When you click on the **Abort Plate(s)** or the **Abort All Plates** button, the system will take some time to respond because it has to communi-

*cate with the instrument to alter all the processing information that has been downloaded to the instrument at the start of the run.*

---

#### **4.8.5.1 Consequences of a System Pause**

If the system is paused and you remove some sample or reagent racks before their processing is completed, see chapter 4.10.2 on page 4-69 and chapter 4.10.3 on page 4-69.

If the system is paused but you resume the run without removing any racks, the processing continues normally (for all non-aborted plates). The pause duration is mentioned in the **Title Block** section of the **Result Report**. These results should be closely examined by a user who will validate them or not, depending on why the system was paused and for how long, and on whether the samples may have been tampered with.

The **Event Log** lets you know at which stage of the process a pause occurred. Taking into account the results obtained on the control wells and/or on the standards and referring to the kit insert may also be helpful in assessing the potential impact of the pause on the analysis.

## 4.8.6 Pipetting Errors/Manual Pipetting

Depending on what has been defined in the assay (see "Assay Programming Manual"), when pipetting errors (insufficient liquid, clot, pipettor hardware error...) occur, the system will either:

- **Raise alarm and stop:** In this case, a specific error message is displayed on the screen explaining the problem and what the operator can do (e.g. Abort, Retry, Ignore...).
- **Log and continue:** In this case, the error is documented (log and flag) but the run continues without any operator intervention.
- or order the operator to **Manually pipette** at end of step (see below).

Whatever the case, the pipetting error is entered in the **Event log** and the affected samples / controls are flagged in the **Combined Report** (see chapter 4.9.2 on page 4-61).

### 4.8.6.1 Manual Pipetting

When manual pipetting is required, the system displays a message indicating precisely what to pipette and where.

If the manual pipetting needs to be done into a test plate, the appropriate plate is automatically moved to its load / unload position.

The instrument is unlocked and you can access other resources (dilution plates, sample racks...) as required to perform the manual pipetting.



---

*If you need to pull out racks, please make sure to put them back exactly in the same position! Make sure everything is reloaded before clicking on the OK button in the above message.*

---

## 4.8.7 Emergency Stop/Cancelling a Run

If you need to stop the processing immediately, what you can do is:



- In the software, click on the **Stop** button in the toolbar. This will open the **System Paused** dialog (see chapter 4.8.5 on page 4-55) and unlock the instrument so that you can open the cover flap and access the work area (in case of liquid overflow, see chapter 8.6.3 on page 8-13).
  - If the problem can be corrected, you can choose to continue the processing by clicking the **Resume** button of the **System Paused** dialog.
  - If the problem cannot be corrected rapidly, you can choose to abort the processing of one plate (highlight the plate and click the **Abort Plate(s)** button) or to cancel the run altogether by clicking **Abort All Plates**.

## 4.9 End of Run/Result Report Window

On the **Elisys Duo** system, it is not necessary to wait for the entire processing to be finished to view the results. As soon as the processing of one test plate is finished, the system generates the result file for this plate.



*To prevent wrong results it is essential to check the result report carefully on flags, entries in the event list or other irregularities.*



*The system generates one result file per plate (not per worklist or per assay). When several assays have been processed on the same plate, see chapter 5.3.3.5 on page 5-22.*

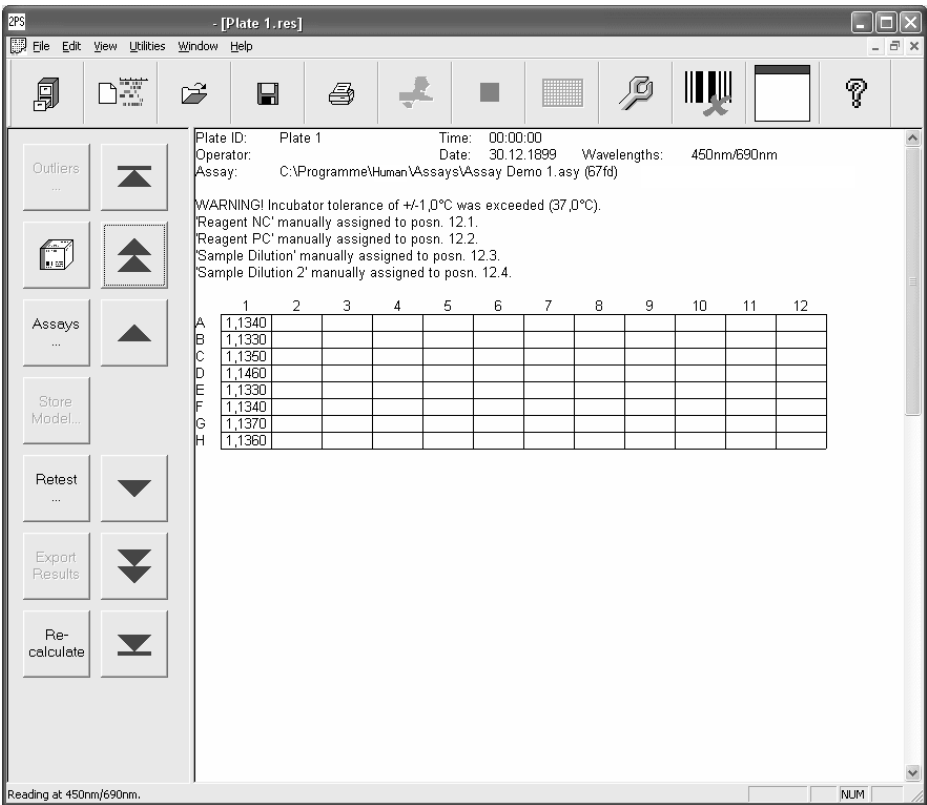


Figure 4-18: Result window

Function	Symbol	Description	Chapter
Assays		This function allows you to recalculate the results with another assay protocol while retaining the original OD values of your plate.	chapter 5.5.4.3 on page 5-42


Function	Symbol	Description	Chapter
Export Results		This function allows you to export test results to a host computer either through an ASTM link or as a (*.txt) file.	chapter 4.9.5 on page 4-66
Lot Specific Values		Opens the Lot Specific Values dialog box to show or edit the required reagents information.	chapter 4.5 on page 4-11 and chapter 5.5.4.2 on page 5-42
Outliers		The Outliers function allows you to manually remove from the results some OD values which you think are not consistent with the test.	chapter 5.5.4.1 on page 5-40
Recalculate		This function allows you to recalculation the results again.	chapter 5.5.4.4 on page 5-43
Retest		<p>In most cases, if a sample is found to be reactive in a first test, at least one re-testing is required to confirm (or infirm) the result obtained in the first test and the sample status as positive (or negative).</p> <p>The re-testing of reactive samples can be ordered manually, on a case by case basis, after examining the results of the first test.</p> <p><b>Note:</b> The retest function can only be used for assays that do not use multiple determination.</p> <p><b>Note:</b> Do not remove outliers or assign assays while the retest function is working.</p>	-
Store Model		This function allows you to save the statistic model used for the calculation of the quantitative results so that they can be used in a new assay.	(see 'Assay Programming Manual')

Table 4-11: Functions of the result report window

## **4.9.1 Structure of the Result Report**

The exact structure of the **Result Report** (and printout) depends on what has been specified for that particular assay when it was defined (see "Assay Programming Manual").

### **4.9.1.1 Title Block**

The **Title Block** section identifies the test that has been performed. It provides information on:

- The Plate ID.
- The person responsible for running the test.
- The assay used.
- The date and time of the test performance.
- Certain default settings such as the upper cut-off and the wavelength as well as the reference wavelength of the photometric measurement.



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*Important error messages that come up in the course of processing the work-list are also displayed here.*

---

### **4.9.1.2 Laboratory Details**

This section provides information on the laboratory where the test has been performed.

The information displayed (e.g. name, address) reflects the data that has been entered in the **Laboratory** tab of the **Options** dialog (see chapter 7.1.5 on page 7-7).

### **4.9.1.3 Incubation Results**

This section shows the incubation parameters. If incubation problems occurred during the run, this is shown directly in the **Title block** part of the report.

### **4.9.1.4 Reader**

This section shows the OD values read by the photometer.

### **4.9.1.5 Validation Criteria**

The data displayed in this section indicate if the control values of the test meet the defaulted criteria.

If the values of the control wells are within the limits specified by the formula in this field, the test is considered valid and can therefore be evaluated. The word "PASSED" is displayed next to each criteria.

If one of the criteria failed, the test will not be evaluated. In this case, the word "FAILED" is displayed next to each criteria.

### **4.9.1.6 Quantitative Results**

This section shows the graph which is created with the standards defined in the assay (see "Assay Programming Manual").



#### 4.9.1.7 Qualitative Results

This section provides information regarding the cut-off value of the test. The parameters and terms used are set during assay definition (for details, (see "Assay Programming Manual")).

#### 4.9.1.8 Spreadsheet Results

This section shows the results calculated according to the rules specified in the assay but on the basis of reference values entered by the user instead of values read by the photometer (see "Assay Programming Manual").

The data reduction of an assay can use up to four spreadsheet settings. Each individual result of the four spreadsheet settings can be included in the Result Report.

#### 4.9.1.9 Events

This section displays error messages as well as messages about user interaction taken from the **Active event log** (see chapter 4.6.6 on page 4-23)

#### 4.9.1.10 Combined Report

The **Combined report** is an important part of the **Result Report** because it gives a view of the results per sample (Patient ID) (see chapter 4.9.2 on page 4-61).

#### 4.9.1.11 Verify Dispense

If one or more Dispense verification steps were included in the assay processed on the plate, the Result Report includes a corresponding number of Verify Dispense sections. In these, you can check if some wells have not been correctly pipetted/dispensed into.



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*In any section, one or more wildcard signs, (\*) or (\*\*\*\*\*) generally indicate that no value could be read (e.g. if you are using the system in Demo Mode or if some wells were inadequately dispensed...) or that no result could be calculated/evaluated (e.g. if the values read were not with the set validation criteria).*

---

### 4.9.2 Result Interpretation

Accurate result interpretation depends on the assay that was processed in the test run. Only a general outline is given here.

#### Per Plate

The first part of the Result Report (all sections except the **Combined Report**) gives you a global view of the test run per plate. You can trace who the operator was, what reagents and batches were used, you can check if the incubation steps were correctly carried out, you can detect any discrepancy in the OD values (e.g. according to the locations of the wells on the plate), you can check if controls met the validation criteria, if some wells were removed due to bad pipetting, etc.

Make sure to note any **WARNING!** line(s) in the **Title Block** section. If your Result Report includes an **Events** section, check the red lines to see if any critical event occurred during the run.

#### Per Sample

The Combined Report, on the other hand, gives you the results per Patient ID. The precise data fields included in the **Combined Report** depend on what has been specified for each assay (see "Assay Programming Manual"). The order in which samples are listed in the Combined Report depends on the option selected in the complete **Patient Editor** dialog (see chapter 5.2 on page 5-4).

#### 4.9.2.1 Flags

Flagged results are not necessarily wrong results. A flag indicates that something happened during the run that may have affected the result on this sample.

The software uses different flags to give an indication of the type of problem encountered:

Flag:	Description:
Clot	Clot detected. Results for flagged samples are not calculated.
IncKo	Incubation overrun. This flag is used when there is a discrepancy between the incubation temperature/time actually observed during a run and the incubation temperature/time defined in the assay. Results for all samples on an incorrectly incubated plate are not calculated.
InsLiq	Insufficient liquid detected. Results for flagged samples are not calculated.
ManID	Manual ID. This flag is used if a sample ID has been manually assigned (see chapter 4.3 on page 4-5). This does not affect result calculation (the results are calculated). If a manually assigned sample is used for several assays (through direct pipetting or through pipetting of the same predilution made from this sample), the ManID flag is included in the Result Report for each assay.
ManPip	Manually pipetted resource. This flag is used when controls or samples have been manually pipetted into the test plate (see chapter 4.8.6.1 on page 4-57). This does not affect result calculation (the results are calculated).
NoLiq	No liquid detected. Results for flagged samples are not calculated.
PipErr	Pipettor hardware error. Results for flagged samples are not calculated.
REAG EXP	Reagent Expired. This flag is used when a reagent was used after its expiry date. When an expired reagent is loaded and identified, the user is warned that the expiry date has been reached/exceeded but can choose to override the warning and still use the reagent for the run. This does not affect result calculation (the results are calculated).
RgtRem	Reagent rack removed. This flag is used if a reagent rack has been removed during processing (see chapter 4.10.3 on page 4-69). This does not affect result calculation (the results are calculated).
SpIRem	Sample rack removed. This flag is used if a sample rack has been removed before it had been completely pipetted (see chapter 4.10.2.2 on page 4-69). No results are calculated for samples that had not yet been pipetted at that stage.
VCFail	Validation criteria failure. Results for flagged samples are not calculated.
VDFail	Verify dispense failure. This flag is used when a reagent/sample/control has not been correctly dispensed into a well. Results for flagged samples are not calculated.

Table 4-12: Flags

When results are flagged but calculated, it is the user's responsibility to check the Result Report and the Active event log, to find out precisely why a particular result was flagged. Only then will it be possible to determine whether the result can be accepted as valid or if the sample must be re-tested.

When results are flagged and not calculated, it is possible, in some cases, to force the system to calculate the results in spite of the problem that occurred. This is done via the **Outliers** function (see chapter 5.5.4.1 on page 5-40).

### 4.9.3 Save/Open the Result Report

The Result report is automatically saved to a result file. By default, this result file is saved in the C:\Programme\Human\Results directory. By default, the name of the result file is the name of the Plate ID, plus a (\*.res) extension.

#### Save

To save the result file under a specific name:

**To do this:**

1. Click on the **File > Save Result as** menu item.
2. The **Save As** dialog is shown (see chapter 3.4 on page 3-14). Enter an appropriate file name and save the reagent report. (Reagent layout files have a (\*.res) extension.)

**File name in case of recalculated/changed results:**

If the results are changed for any reason and the file is saved again then the software creates a backup of the original result file before saving the changes. The backup will have the same basic filename but with a revision index appended. The revision index will start at "0" and will automatically increment whenever a new file is saved.

For example, if "Plate\_07030601.res" is changed and saved again the original result file will be backed up as "Plate\_070306010.res".

#### Open

**To do this:**

1. Click on the **Open** button.
2. In the **Open** dialog (see chapter 3.3 on page 3-11) which is displayed, select the entry **Result Files (\*.res)**.
3. Select the desired (\*.res) file and open it.  
The file is loaded and the calculation is performed again before it is displayed.

### 4.9.4 Print the Result Report

**To print the complete Result report:**



1. Click on the **Print** button (see chapter 3.5 on page 3-16).



---

*If you had checked the **Automatically print result** item in the **Worklist Options** dialog (see chapter 5.4 on page 5-24), the Result report will be automatically printed each time it is generated.*

---

## 4.9.5 Export the Results



---

*Required access rights: Post Results to LIMS*

---

The **Elisys Duo** system can export test results to a host computer either through an ASTM link or as a (\*.txt) file.

The export of test results can be ordered individually by the operator once a result report is displayed on the screen or the **Elisys Duo** software can be configured to systematically export the results. The choice between these two possibilities will generally depend on whether the user wants to examine and validate the results before exporting them or whether the validation will be done at host computer level.

For more information on result exports, see chapter 6.1.4 on page 6-11. On the format, structure and contents of (\*.txt) export files, (see "Assay Programming Manual"). On ASTM export of test results, see chapter 6.2.5.2 on page 6-20.

## 4.10 Unloading



*Inspect instrument deck, plates, racks, etc. for spillages. If there are spillages, check instrument for leakages (see chapter 8.2 on page 8-3).*

### 4.10.1 Unload Test Plates



*Inspect test plates after unloading for unexpected or irregular fill heights.*

#### 4.10.1.1 At the End of the Run - Basic Procedure

By default, fully processed plates ("finished plates") are stored on the instrument in the room-temperature incubators.

Then, once the processing of the complete worklist is finished, the system prompts you to start unloading the plates by displaying the following message:



Figure 4-19: Remove plate message

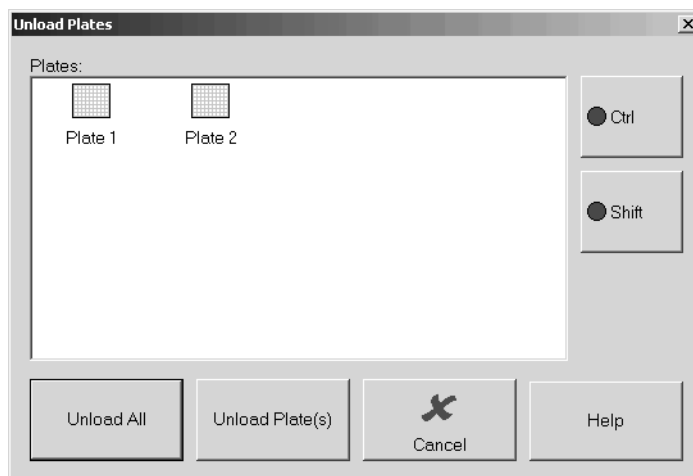
#### To remove the test plate:

1. Open the cover of the instrument.
2. Remove the test plate.
3. Close the cover of the instrument.
4. Click on the OK button to confirm removal in the software.

#### 4.10.1.2 Before the End of the Run - Fully processed Plates

If some plates are already fully processed and you want to unload them before waiting for the end of the run:

1. Select the Edit > Unload Finished Plates menu item. This opens the Unload Plates dialog.



*Figure 4-20: Unload Plates dialog*

2. In the list, select the plate or plates that you want to unload and click **Unload Plate(s)** or simply click **Unload All** if you want to unload all the plates listed. **Only fully processed plates are shown in the list.**
3. Remove the plate(s) (see chapter 4.10.1.1 on page 4-67)

Choosing to unload finished plates before the end of the run can be useful for example if you want to visualize a plate in which some wells have been incorrectly pipetted or if you want to further process a plate manually or on another instrument. You do not need to use this procedure if you intend to reload additional samples and plates using the "Continuous Loading" feature. In this case, the system automatically lets you remove fully processed plates before allowing you to reload new plates (see chapter 5.6.5 on page 5-47).

#### 4.10.1.3 Before the End of the Run - Unfinished plates

The only way to remove plates that are not fully processed is by using the pause and test plate removal procedure (see chapter 4.8.5 on page 4-55).



## 4.10.2 Unload Sample Racks

### 4.10.2.1 At the End of the Run

To remove/unload a rack at the end of a run:

1. Pull out the rack(s) designated by a flashing LED.

### 4.10.2.2 Before the End of the Run

Technically, it is possible to remove a rack from the instrument even while the run is still being processed.

Two cases have to be considered: either the rack which you want to remove is fully processed or it is not.

A rack is fully processed when all the pipetting operations out of that rack has been completed (i.e. that rack will not be needed for the rest of the run). You know that a rack is fully processed when the corresponding LED starts flashing. Removing fully processed racks is necessary for instance if you want to reload new samples on Continuous Loading, see chapter 5.6.2 on page 5-46).

If the rack is fully processed (and the LED is flashing):

1. Pull out the rack(s) designated by a flashing LED.

If the rack is not yet fully processed (the corresponding red LED is not flashing) **you should NOT remove it**. If there is a specific problem and you absolutely have to remove it, do so as described above (except that no LED is flashing).



*Note, however, that if you remove and reload a sample rack that was not fully processed, any sample that will be pipetted from that rack after you have removed and reloaded it will be flagged SpIRem and that the respective results will not be calculated (see chapter 4.9.2 on page 4-61).*

## 4.10.3 Unload Reagent Racks

Basically, the rules that apply to reagent racks are equivalent to those described for sample racks, i.e.:

- Technically, it is always possible to remove a reagent rack, even while the run is being performed.
- You should not remove a reagent rack before it is fully processed (i.e. the corresponding LED is flashing) unless you absolutely need to do so or are prompted to do so by the software (see below).

However, the following differences apply:

- If you remove a reagent rack before it is fully processed, all the samples which had not yet been pipetted when the rack was removed will be flagged **RegtRem** but the corresponding results will still be calculated.
- If you need to load an unstable reagent, the system will direct you to do so as described in (see chapter 4.7.4 on page 4-39) and the samples will not be flagged.

Unloading a reagent rack (during or at the end of a run) is done as described above for sample racks.

#### 4.10.4 Unload Tip Racks and Dilution Plates

The cover is normally locked during the whole run (it can be unlocked only for a short time when it is necessary to reload tip racks, see (see chapter 4.7.6 on page 4-42).

You will have to wait until the end of the run to unload dilution plates and tip racks.

**To remove them:**

1. Open the cover.
2. Take dilution plate(s) or empty tip racks out of the respective holding devices.
3. Close the cover.



---

*If you are using the **Re-use partial tip racks** option (see chapter 5.4 on page 5-24), remove tip racks only if they are completely empty. DO NOT remove partially empty racks! The system monitors the number of tips left and will include them in planning the next worklist.*

---

#### 4.10.5 Unload Other Resources

Clean fluid and system liquid do not need to be emptied or unloaded after each run. For wash buffers, follow the storage conditions in assay kit inserts.

For additional information, refer to the maintenance plan and procedures.

#### 4.10.6 Unload Waste Disposal

- Dispose of test plates, dilution plates and sample tubes in accordance with legal regulations for biological hazardous waste.
- Visually check the contents of the tip ejection waste container. There is no sensor for this container. If full or nearly full, replace as described in chapter 8.2.3 on page 8-5.
- Check the liquid waste level in the liquid waste container. If full or nearly full, empty and clean as described in chapter 8.2.3 on page 8-5.

## 4.11 Shut Down / End of Day Maintenance

### Procedure



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*Before shut down the system see Maintenance procedures in chapter 8.2.3 on page 8-5.*

---



---

*Always shutdown the computer (Windows shutdown) before switch off the system! Otherwise the computer could lose data or could get hard-disk failures.*

---

1. Click on the File > Exit menu item to terminate the **Elisys Duo** software.
2. Click on the Start > Shutdown menu item of the Windows operating system.
3. Select the Shutdown item.
4. Click on the OK button.  
The software system is shut down and the PC is switched off automatically.
5. Switch off the **Elisys Duo** system.
6. Inspect and clean the instrument as described in chapter 8.2.3 on page 8-5.
7. Observe the complete maintenance instructions (see chapter 8 on page 8-1).

## Use of the System

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Shut Down / End of Day Maintenance

## 5 Advanced Functions

This chapter describes further functions of the **Elisys Duo** software.

### 5.1 Initialisation and Selftest



*Required access rights: Nothing*



***Never use the loading bay as storage space! The moving bar code scanner could be damaged or stored objects could be upset.***



***Only load or unload on the indicated lane. Wait for a load/unload message! Wait until the bar code scanner stands idle!***



***Never reach on the right side of the bar code scanner into the loading bay! The bar code scanner could crash into your hand, when it drives back.***



A selftest is performed each time you start the **Elisys Duo** software. The system is initialised and checks all instrument modules. These are checked as follows:

COP (Command Operating Processor)	An EEPROM checksum is created. The serial connection to all modules of the <b>Elisys Duo</b> is verified.
Pipettor	The pipettor is initialised. The movement in x-, y-, z-axis is checked, the encoders and the home sensors in these directions are tested. The pipettor is primed with system liquid five times.
Washer	The home sensors, encoders, aspirate and dispense pump are checked.
Photometer	An EEPROM checksum is created. The reference voltages of the front end and also the photodiode dark background signals is measured. Each filter is tested to choose the optimum read gain and for noise at optimum gain. The optic channel transmissions are measured.
Plate Transport	A EEPROM checksum is created. The movement in x-, y-, z-axis is checked and the encoders in these directions are tested.

#### Incubators

A EEPROM checksum is created. The temperature sensors are tested and it is checked if the heater drives are not in open circuit.

The results of this instrument check is then displayed on the screen:

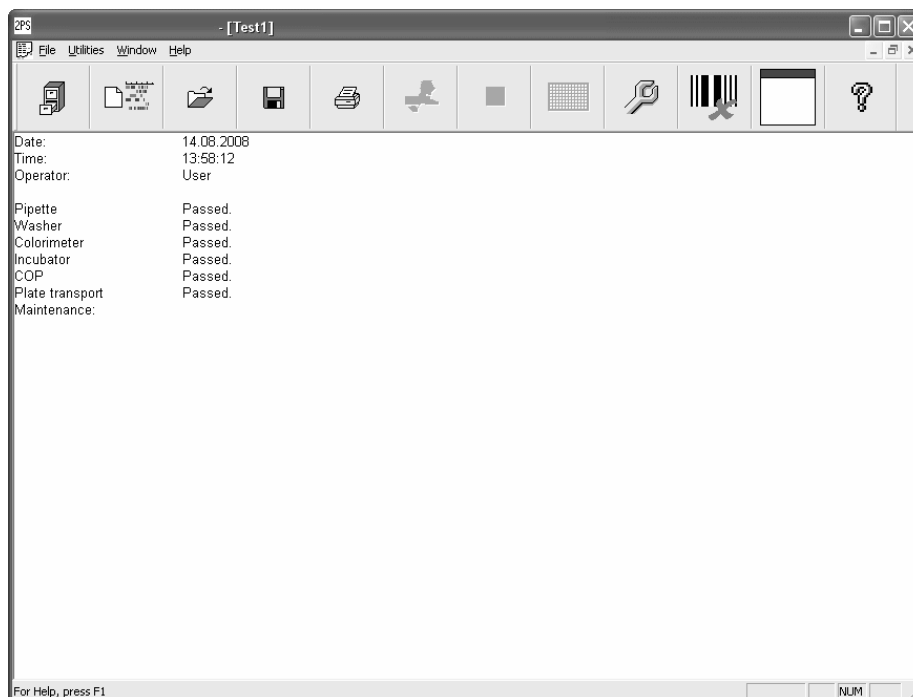


Figure 5-1: Selftest report

The result of the selftest is satisfactory if the word "Passed" is displayed for each instrument module.

The Maintenance field remains empty unless you have defined specific maintenance checks to be performed by the system (see chapter 8.5 on page 8-10).

Under default settings, self tests are performed only each time you start the software. But other options are available.

### 5.1.1 Manually Start Selftest

The **Elisys Duo** system allows the user to request a selftest punctually at any other time (not, however, while a worklist is being processed). This is useful, for example, if you suspect that an instrument module is not responding or functioning correctly.

To do this:

1. Select **Selftest** in the **Utilities** menu.  
After a confirmation dialog, a selftest will be immediately performed and the results shown as above.

### 5.1.2 Selftest before each Run



---

*Required access rights: Change system setup*

---

1. Select the **Utilities > System Setup** menu item to open the **System** tab of the **System Set-Up** dialog (see chapter 7.2.1 on page 7-12).
2. Check the **Perform self-diagnostics before a run** item in the **Self-diagnostics** area.

This dialog also lets you program the software to automatically print a report each time a selftest is performed.

To do this:

3. Check the **Auto print self-diagnostics report** item in the **Self-diagnostics** area.

If this item is not checked, select **File > Print** or click the **Print** button in the toolbar to print a selftest report.



---

*Performing a selftest check before each run is a good safety procedure. However, it takes time (approx. 2 minutes), and is recommended mostly for operators who are not familiar with the system.*

---

### 5.1.3 Selftest Failures

If one or more of the instrument modules that are checked during the selftest are found to be not responding correctly, a corresponding error message will be displayed in the selftest report.

Before interfering with the faulty or non-responding module, try to perform the selftest again by selecting **Selftest** in the **Utilities** menu.

If this also fails, refer to the error message list in chapter 9.1 on page 9-1 and check what corresponding action can be undertaken to solve the problem.

## 5.2 Complete Patient Editor



*Required access rights: Edit patient details*

The complete Patient Editor dialog allows the direct input of patient data and the assignment of assays. It is required in the following situations:

- If you prefer to assign tests before loading the samples on the instrument.
- If you have already created a new worklist (see chapter 5.3 on page 5-13) and have not yet assigned tests to some patients.
- If you are reusing a formerly saved worklist and want to assign the tests to some new patients.
- If only samples without bar coded tubes are used.
- If additional patient data (e.g. name, sex, date of birth etc.) are to be entered.
- If you are using the software in demo mode.

To enter patient data manually:



Select the Utilities > Patient Details menu item. The **Elisys Duo** software shows the complete Patient Editor dialog:

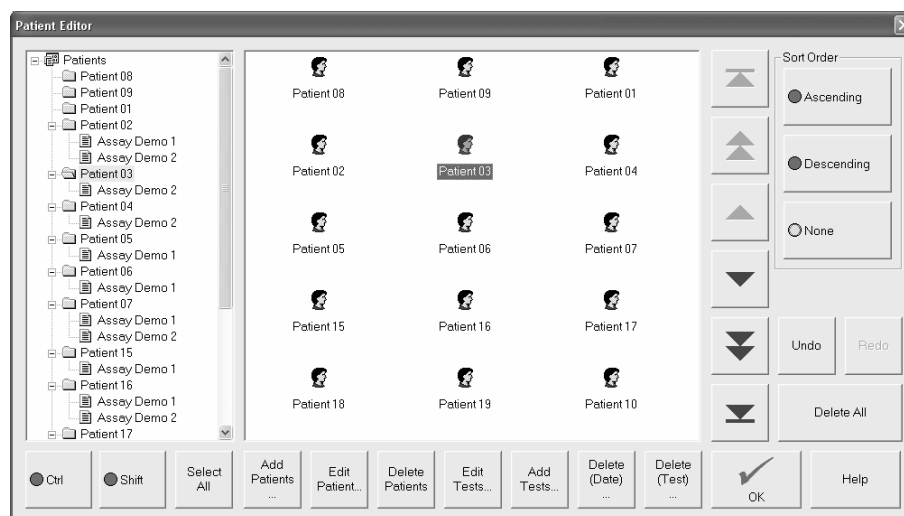


Figure 5-2: Complete Patient Editor dialog

Left list	Shows all patients and its assigned assays as a tree. (Click on the plus sign to display the assays.)
-----------	---



Right list	<p>Shows all patients.</p> <p>Select only one patient to:</p> <ul style="list-style-type: none"><li>• edit the patient details, or</li><li>• edit the assigned assays</li></ul> <p>Select one patient or several patients to:</p> <ul style="list-style-type: none"><li>• delete the patient/patients, or</li><li>• add assays.</li></ul>
------------	---

Function	Description
Add Patients	New patients ID can be created with this function (see chapter 5.2.1 on page 5-7).
Add Tests	This function allows the assignment of patients and assays (see chapter 5.2.3 on page 5-10).
Delete All	All created patients can be deleted with this function.
Delete (Date)	This function allows the deletion of patients already created which were created before a certain date.
Delete Patients	Patients already created and selected can be deleted again with this function.
Delete (Test)	Allows the deletion of the assignment of certain assay to all patients.
Edit Patient	Additional detail (e.g. name, sex) can be entered for a selected patient by means of this function (see chapter 5.2.2 on page 5-8).
Edit Tests	With this function, the assignment of a selected patient and the assigned assay can be changed (see chapter 5.2.4 on page 5-12).
Select All	All created patients can be selected with this function.
Sort Order	<p>The <b>Sort Order</b> field allows you to define the order in which the samples will be pipetted from the tubes.</p> <p>The <b>Sort Order</b> selected also serves to determine:</p> <ul style="list-style-type: none"> <li>the samples' order for the <b>Auto Arrange</b> function in the <b>Load</b> dialog (see chapter 4.7.1 on page 4-30)</li> <li>the order in which samples are listed in the results (in the <b>Combined Report</b>)</li> <li>the order in which sample IDs will be sorted in the <b>Patient Editor</b> after a successful worklist import.</li> </ul> <p>Selectable sort order:</p> <ul style="list-style-type: none"> <li><b>Ascending:</b> Sorted in alphanumeric ascending order (based on the sample IDs entered or read by the bar code scanner).</li> <li><b>Descending:</b> Sorted in alphanumeric descending order (based on the sample IDs entered or read by the bar code scanner).</li> <li><b>None:</b> The samples will be pipetted from the tubes in the order in which they are placed in the racks.</li> </ul>

Table 5-1: Functions of the Patient Editor dialog

## 5.2.1 Add new Patients

If the button **Add Patients** has been clicked in the complete Patient Editor dialog, the **Add Patient(s)** dialog is displayed:

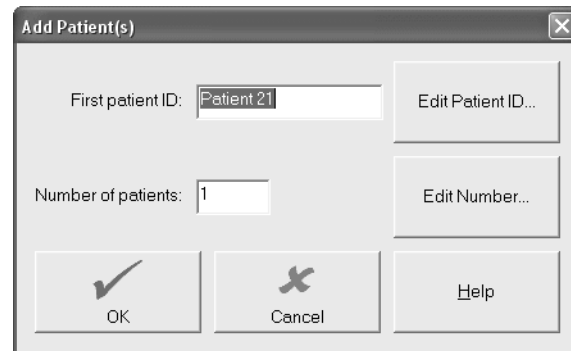


Figure 5-3: Add Patient(s) dialog

Function	Description
First patient ID	In this box, the (first) patient ID number can be entered. For the input of the patient ID, the <b>Edit Patient ID</b> dialog can be used (see chapter 3.6.1 on page 3-21).
Number of patients	In this box, the number of patients to be created with a consecutive patient ID can be entered. Example: Input: ID: P0001; Number: 5 Result: P0001, P0002, P0003, P0004, P0005  For the entry of the value, click on the <b>Edit a Number</b> button (see chapter 3.6.2 on page 3-23).

Table 5-2: Functions of the Add Patient(s) dialog



*The entered patient IDs must be unique! If non-unique patient IDs are used (e.g. same ID for different persons at different worklists), the patient database is incorrect. In this case, features like patient history or patient result report must not be used.*

## 5.2.2 Edit Patient Details

Only the Patient ID is absolutely needed to process a test run. However, the **Elisys Duo** system also allows the user to enter and store the following patient details:

- last name
- birth date
- sex

The screenshot shows a 'Patient Details' dialog box. It has a title bar with a close button. The main area contains three input fields: 'Practice Assigned Patient ID' (containing 'Patient 02'), 'Last Name' (empty), and 'Birthdate' (containing 'Donnerstag, 17. Juli 2'). Each field has an 'Edit...' button to its right. Below the 'Birthdate' field, there are three smaller buttons: 'Year...', 'Month...', and 'Day...'. At the bottom of the dialog, there are three buttons: 'OK' (with a checkmark icon), 'Cancel' (with an 'X' icon), and 'Help'.

Figure 5-4: Patient Details dialog

Function	Description
Practice Assigned Patient ID	In this box, the selected patient ID number can be changed. Please note that the patient ID must remain unique. It is also possible to click on the <b>E d i t</b> button to open the <b>E d i t T e x t</b> dialog (see chapter 3.6.1 on page 3-21).
Last Name	In this box, the last name of the patient can be entered. It is also possible to click on the <b>E d i t</b> button to open the <b>E d i t T e x t</b> dialog (see chapter 3.6.1 on page 3-21).
Birthdate	After the activation of this option, the date of birth of the patient can be selected in the adjoining box. For a simplified entry of the date of birth, a calendar is available which is opened after clicking on the arrow.
Year, Month, and Day	The date of birth can also be entered by pushing the buttons. After pushing, the <b>Enter a Number</b> dialog is opened (see chapter 3.6.2 on page 3-23).
Patient Sex	After pushing the button <b>E d i t</b> a dialog appears for selecting the sex of the patient. The following selection options are available: <ul style="list-style-type: none"> <li>• <b>F</b>: female</li> <li>• <b>M</b>: male</li> <li>• <b>U</b>: undefined/unknown</li> </ul>

Table 5-3: Functions of the Patient Details dialog



*If you are using bar codes or importing test orders from a host computer, the patient details can be entered automatically provided the pertinent information is included in the bar code or in the imported file/data.*

### 5.2.3 Assign Assays to the Samples (Complete Patient Editor)

Before a sample can be tested, an assay must be assigned to the sample. This assignment is made in two steps:

- In the first step, all samples must be selected which are to be assigned to an assay.
- In the second step, the required assays are selected.

#### Procedure

1. Select all involved patients in the complete patient editor.
2. Press on the Add Tests button.  
The Select Assay(s) dialogs opened:

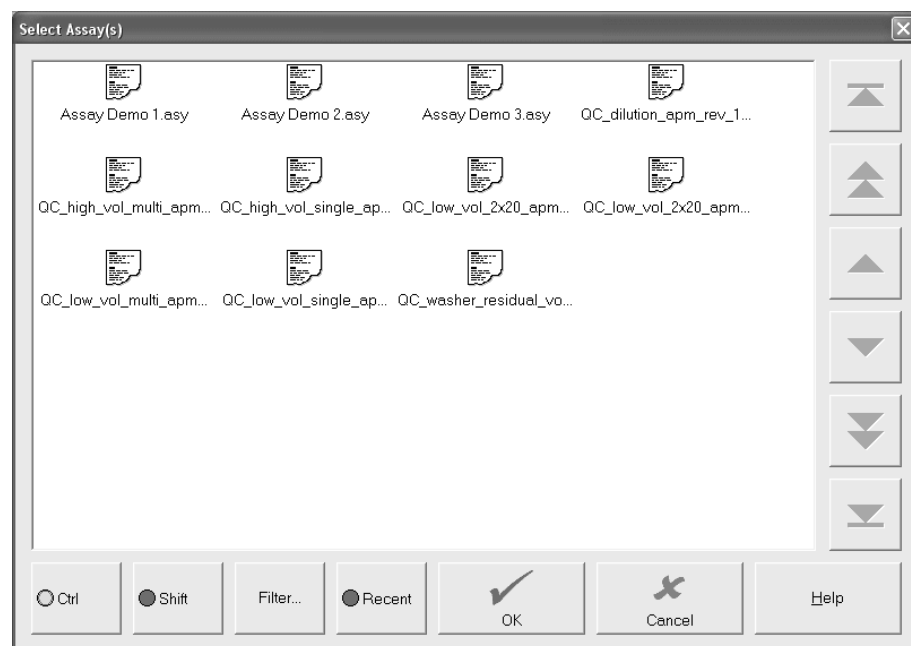


Figure 5-5: Select Assay(s) dialog

Function	Description
Filter	<p>With this function, the number of assays displayed can be limited.</p> <p>After pushing the button, the Edit Text dialog (see chapter 3.6.1 on page 3-21) is opened. After the entry, only those assays containing the entered text are displayed. The filter ignores capitalisation.</p> <p>Example: Filter input: igg Displayed Assays: CMV IgG, HSV IgG, MUMPS IgG, Toxo IgG</p>
Recent	<p>After clicking on this function, only assays are displayed which have already been used once in a worklist.</p> <p>If this function is clicked on again, all assays are displayed again.</p>

*Table 5-4: Functions of the Select Assay(s) dialog*

After the selection of the assays and the pushing of the OK button, the Patient Editor dialog appears again. The assignment of patients and assays is now executed.

### 5.2.4 Edit Assigned Assays

With this function, the assignment of a selected patient and the assigned assay can be changed.

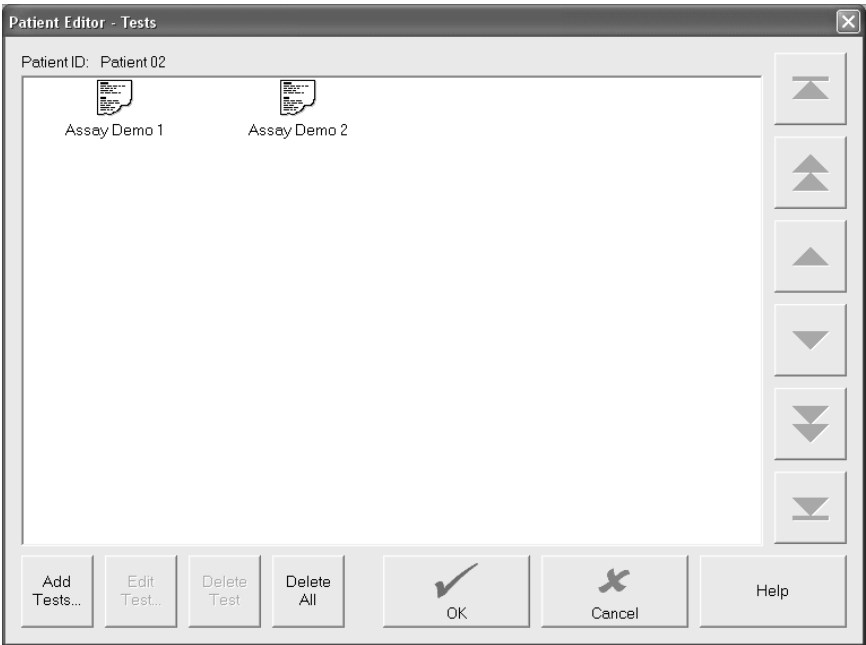


Figure 5-6: Patient Editor - Tests dialog

Function	Description
Add Tests	This function allows the assignment of the patient and assays (see chapter 5.2.3 on page 5-10).
Edit Test	Shows the Test Order Details dialog to add/edit the collection date of the selected assay.
Delete Test	Selected tests can be deleted with this function.
Delete All	All assigned assays can be deleted with this function.

Table 5-5: Functions of the Patient Editor - Tests dialog



## 5.3 Create your own Worklist



---

### *Required access rights: Start Worklists*

---

The worklist is at the core of how the **Elisys Duo** system operates.

In the **Patient Editor** dialog, you defined the tests (assays) to be performed for each sample (e.g. sample 000001 must be tested for HIV and Hepatitis, sample 000002 must be tested for HIV only, sample 000003 must be tested for HIV, Hepatitis and Toxoplasmosis, etc.).

Now, you will use the worklist to define how these tests will actually be implemented on the test plates (e.g. Plate 1 will be used to test sample 000001, 000002 and 000003 for HIV, Plate 2 will be used to test sample 000001 and 000003 for Hepatitis, and Plate 3 will be used to test sample 000003 for Toxoplasmosis ...).

Once the worklist is defined, the system checks all parameters and signals any error. Errors must be corrected before you start a run.

A new worklist is generally created for each test run but if similar test runs are performed regularly, the system allows the user to save and re-use previously defined panels.

The main element of worklist definition is the **Set-Up Panel** dialog. Here, the user organizes the test run to be performed: which assay on which plate and the order of the plates.

The **Set-Up Panel** dialog is blank when it opens, i.e. when the system does not yet have the required information on the samples or on the tests to generate a suggested worklist.

Use this method particularly if:

- you create a worklist before loading the sample racks onto the instrument.
- you do not import data from a host computer.
- you are using the system in demo mode (see chapter 5.10 on page 5-54).

If you have already loaded the sample racks and assigned assays to samples as described in chapter 4.3 on page 4-5, or if you have imported patient data and test orders from a host computer, the system will automatically suggest a worklist; you can refer directly to chapter 4.4 on page 4-10.

### Create a Worklist



1. Click on the new worklist button.  
An empty **Set-Up Panel** dialog is shown (see chapter 5.3.1 on page 5-15).
2. Click on the **Add Plate** button.  
A new plate is added.
3. Click on the **Add Assay** button.  
The **Open** dialog is shown (see chapter 3.3 on page 3-11).
4. Select the desired assay file.  
The assay is added.

5. Click on the **Add Patient** button.  
The **Select Patient(s)** dialog is shown (see chapter 5.3.2 on page 5-19).
6. Select the desired sample(s) and click on the **OK** button.  
The sample(s) are shown in the **Set-Up Panel** dialog.
7. Optional:
  - Click on the **Add Assay** button to add a further assay to the (selected) plate.
  - Click on the **Add Patient** button to add further samples to the (selected) assay.
  - Click on the **Add Plate** button to add a further plate.
  - Click on the **Edit** button to change the name of the (selected) plate.
  - Move the plate order:  
The **Elisys Duo** will process plates in order from top to bottom as shown in the list. The order of the plates can be edited by clicking on the **Move Up/Move Down** buttons.
8. If you are ready, click on the **OK** button.  
The **Elisys Duo** software shows the **Lot Specific Values** dialog (see chapter 4.5 on page 4-11).



---

*The **Elisys Duo** is a two-plate system. However, in order to provide a longer walk-away time, a third plate can be initially loaded, which will be processed usually after the processing of the first plate is finished. Furthermore, it is possible to load more plates during the run. Please refer to the section on continuous loading (see chapter 5.6 on page 5-44) if you add plates during a run.*

---

#### **Maximum number of plates included in a worklist at the same time:**

It is normally possible to add up to 3 plates in the same worklist. This depends, however, on the assays and on the number of samples to be processed. In most cases, the system will then schedule the run so that the processing of the last plate begins only when the processing of the first plates is finished.

If you need to process heavy workloads, it is sometimes preferable to do two consecutive runs (see the end of chapter 4.6.2 on page 4-17 on how to optimize your workflow) or to rely on continuous loading (see chapter 5.6 on page 5-44) rather than add a maximum number of plates in the same worklist.

## 5.3.1 Set-up Panel Dialog

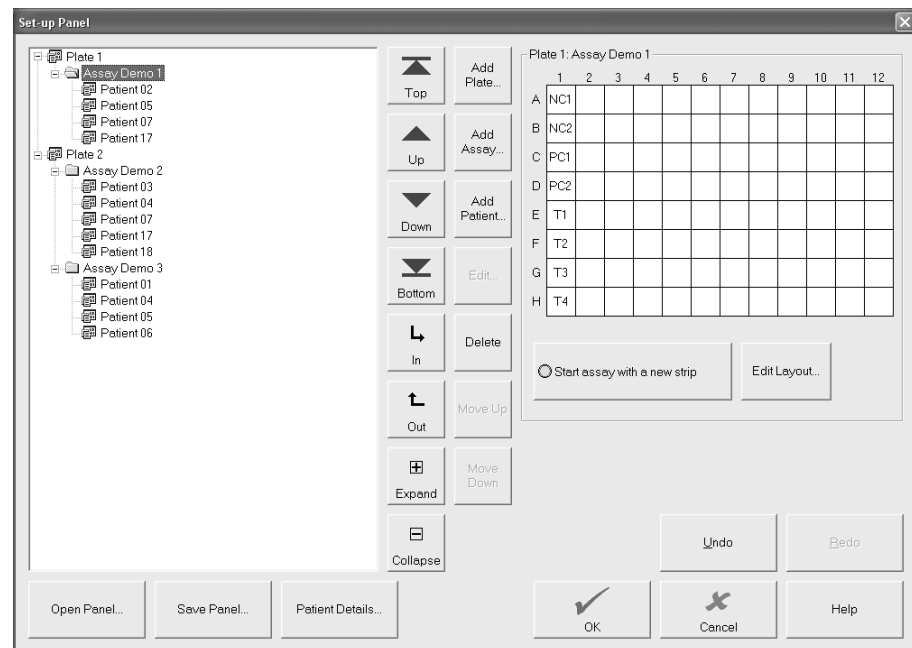






Figure 5-7: Set-up Panel dialog with two plates

Function	Description
Plates, assays and samples	<p>In the tree, all plates are displayed which will be used in the worklist. Later, they are processed in top down sequence. The individual plate can be selected by clicking on them. After the selection, the assignment is indicated in the plate layout.</p> <p>After clicking on the plus sign of a plate or double clicking on the plate, all assays are displayed which will be used on the selected plate. The individual assays can be selected by clicking on them.</p> <p>After clicking on the plus sign of an assay or double clicking on the assay, all samples are displayed which will be processed with the selected assay. The individual samples can be selected by clicking on them.</p>
Add Assay	With this function, you can add a new assay to the (selected) plate. After clicking on the function, an <b>Open</b> dialog for the selection of assays is opened automatically (see chapter 3.3 on page 3-11).
Add Patient	With this function, you can add a new sample to the (selected) assay. After clicking on the function, the <b>Select Patient(s)</b> dialog for selecting the samples is opened automatically (see chapter 5.3.2 on page 5-19).
Add Plate	With this function, you can add a new plate to the worklist. After clicking on the function, the new plate is added.
Collapse 	Opens the complete plates/assays/samples tree.
Delete	With this function, you can delete a selected plate, assay, or sample from the worklist.
Edit	<p>This function allows you to change the plate ID (name) of a (selected) plate.</p> <p>Take care that the plate ID is clear and unique, i.e. is not used by another plate in this worklist yet.</p>
Edit Layout	<p>This function opens the <b>Assay Layout</b> dialog for a selected assay (see chapter 5.3.1.1 on page 5-17).</p> <p>The software ignores any plate layout given by the "Assay Layout" after import of a plate layout when processing the plate (also recalculation of the results).</p>
Expand 	Opens the complete plates/assays/samples tree.
In 	Opens the lower part of the selected plates/assays/samples tree.
Move Down	This function changes the sequence of the plate processing. A plate can be processed <b>after</b> another one.
Move Up	This function changes the sequence of the plate processing. A plate can be processed <b>before</b> another one.
Open Panel	Opens a saved worklist (see chapter 5.3.4 on page 5-23).
Out 	Closes the lower part of the selected plates/assays/samples tree.

Function	Description
Patient Details	With this function, you can open the complete Patient Editor dialog (see chapter 5.2 on page 5-4).
Save Panel	Saves the created worklist (see chapter 5.3.4 on page 5-23).
Start assay with a new strip	By activating this function, you can make sure that the selected assay starts in a new column, even if there are unused wells left in the previous column (see chapter 5.3.3 on page 5-19 and chapter 5.3.3.4 on page 5-21). This function is activated by default.

Table 5-6: Functions of the Set-up Panel dialog

## Plate Layout

The upper right-hand side of the Set-Up Panel dialog shows the plate layout. The 96 cells in this table represent the actual test plate with its 96 wells. Columns are numbered from 1 to 12, and rows are lettered from A to H so that each individual cell/well has a unique location (e.g. E5).

In the plate layout, sample types are precisely labelled (B1, NC1, T3, etc.).

Label:	Description
B	Blank value for background reading
S	Standard
T	Test (sample)
NC	Negative control
PC	Positive control
CO	Cutoff

Table 5-7: Plate layout labels

To help distinguish them visually, a set color is generally assigned to each sample type, e.g. NC wells are green, PC wells are red, T wells are black, etc. These colors are assigned when the assay is defined (see "Assay Programming Manual").

### 5.3.1.1 Editing the Plate Layout

The Plate Layout is the way in which the different samples (samples (T) but also negative control (NC), positive control (PC), standards (S), blank samples (B), etc.) are arranged on a test plate.

This arrangement is specifically defined for each assay when the assay is created, as described in the "Assay Programming Manual".



*If you are using a validated pre-defined assay, you should not attempt to edit the Plate Layout at this stage.*



*Even if you are using your own assays, it is generally not recommended to alter the Plate Layout at this stage as any changes made will apply only*

## Advanced Functions

---

### Create your own Worklist

*to this run (the assay file itself will not be changed so that if you process the assay again later, the original layout will apply).*

---



*At this stage, the best way to optimize the Plate Layout, if you are not processing full plates, is to process several assays per plate and eliminate "empty" wells as explained in (see chapter 5.3.3.4 on page 5-21).*

---

### 5.3.2 Add Patients

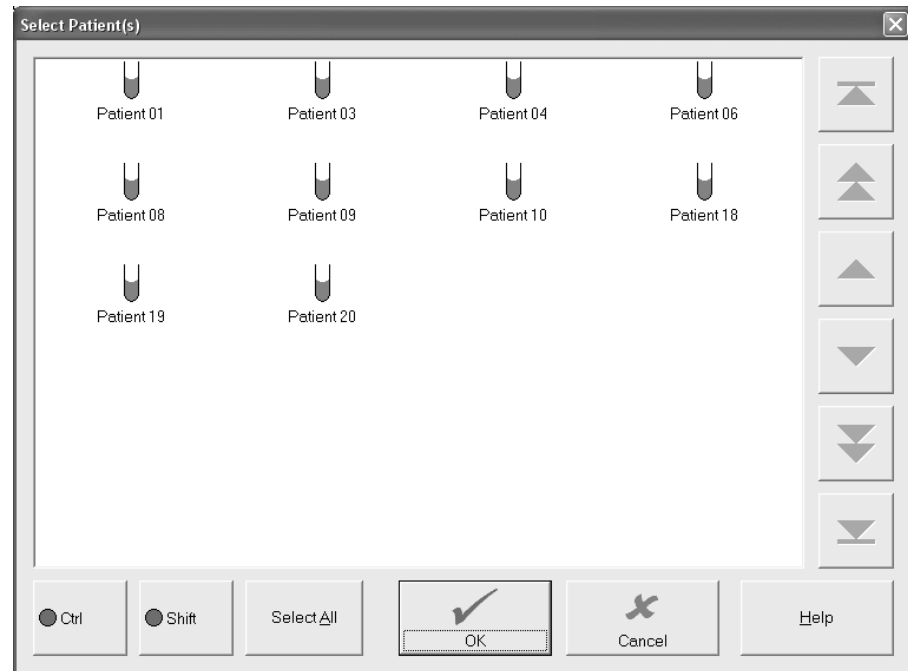


Figure 5-8: Select Patient(s) dialog

Function	Description
Select Loaded	This function allows you to select automatically those samples that are already loaded on the instrument. In the list, those samples are indicated by a (*) sign next to the sample ID.

Table 5-8: Functions of the Select Patient(s) dialog



*If the Select Patient(s) dialog is empty when it opens, this means that you have not already assigned this particular assay to any patients as explained in chapter 5.2 on page 5-4. You can click the Patient Editor button in the Set-up Panel dialog and do this now. If necessary, refer first to the explanations given in that section.*

### 5.3.3 Processing Several Assays per Plate

Combining several assays on the same plate is a way to save time (and test plates) if you intend to test several different assays on a fairly small number of samples (e.g. 8 assays on 20 samples). It is also done on a regular basis for some tests, e.g. Toxo IgG and Toxo IgM.

The **Elisys Duo** system allows you to combine several assays on the same test plate but only if the following conditions are met.

Assays can be combined on the same plate only if:

- They have a compatible assay structure, i.e. compatible parameters for incubation steps, shake steps, conditional delay (if any), reading parameters, etc. and
- They belong to the same assay group.



---

*If one of the assays you intend to combine requires the use of unstable reagents, it is best to place it as the first assay on the plate.*

---



---

*Avoid combining assays with Plate wash mode and assays with Strip wash mode on the same plate! This could result in a delayed final aspiration including on the Plate wash mode assay.*

---



---

*Assays with even small differences in the wash steps (e.g. dispense rate, dispense volume) but requiring elimination assay drift must not be combined on one plate.*

---

#### 5.3.3.1 Compatible Assay Structure / Parameters

To check whether the assays you intend to combine on the same plate have compatible assay structures, you can either open these assays and review their respective parameters as described in (see chapter 4.3 on page 4-5) or use the system to check their compatibility automatically.

If the assays you have tried to combine on the same plate are compatible, the Worklist window is displayed normally (plate status is **Not Loaded**).



---

*The **Elisys Duo** software does not check compatibility of shake steps. If an assay that does not need shaking is combined with a second assay that needs shaking, the plate will be shaken.*

---

If the assays you have tried to combine are not compatible, a warning message is displayed telling you why these assays cannot be combined on the same plate.

If you click on the **OK** button on the warning message, **Error** will appear as the status of the respective plate in the Worklist window. To correct the worklist definition and assign each assay to a different plate, go back to the **Set-Up Panel** dialog (see chapter 5.3 on page 5-13).

#### 5.3.3.2 Assay Combination Groups

Assay combination groups are intended for assays that are commonly processed together. Assigning assays to the same assay group serves to confirm to the system that these assays can be combined on the same plate. Conversely, if assays belong to different combination groups, the system will never allow them to be processed on the same plate (even if their parameters are compatible).

See "**Elisys Duo** Assay Programming Manual" for detailed information.

#### 5.3.3.3 Automatic Worklist Definition

If you import worklist/test orders from the LIS and you use bar coded samples, as soon as you load new samples on the instrument, the system automatically suggests



a suitable worklist to process the samples you just loaded (see chapter 4.4 on page 4-10). This also true when you reload samples in an on-going worklist using the continuous loading procedure (see chapter 5.6 on page 5-44).

Under default settings, whenever a worklist is thus automatically generated by the system, the system always tries to combine as many assays as possible on each plate (provided, of course, that assay parameters are compatible and that the assays belong to the same assay combination group).



*Note, however, that this redefinition applies to the current worklist only. If you decide that there are some assays which you never want to combine on the same plate (even though they have compatible structures), you have to change their combination group as described in the 'Elisys Duo Assay Programming Manual' so that they belong to different groups.*

### 5.3.3.4 Strip Management/Optimizing the Plate Layout

If you use coated microplates with removable strips, when combining several assays on the same plate, you have to make sure that:

- In the software, each assay starts on a new strip.
- You rearrange the microplate you intend to load so that the strips correspond exactly to what has been defined in the software.

#### New Strip

The Set-up Panel dialog includes a Start assay with a new strip checkbox (see chapter 5.3.1 on page 5-15).

If you enable the Start assay with a new strip checkbox (default), you can see that Assay2 now starts on Strip 5 only. This is required if you use coated plates with removable strips. You can then prepare your microplate accordingly.

Plate 1												
	1	2	3	4	5	6	7	8	9	10	11	12
A	NC1	T5	T13	T21	NC1	T5	T13	T21				
B	NC2	T6	T14		NC2	T6	T14					
C	PC1	T7	T15		PC1	T7	T15					
D	PC2	T8	T16		PC2	T8	T16					
E	T1	T9	T17		T1	T9	T17					
F	T2	T10	T18		T2	T10	T18					
G	T3	T11	T19		T3	T11	T19					
H	T4	T12	T20		T4	T12	T20					

Assays: 1-4 Assay1  
5-8 Assay2

Figure 5-9: Two Assays on a plate (start assay with a new strip)

If you combine two assays on the same plate **without** checking this box, the second assay starts immediately after the last well of the first assay as shown below: Assay2 starts in well B4, immediately after the last sample well for Assay1.

Plate 1												
	1	2	3	4	5	6	7	8	9	10	11	12
A	NC1	T5	T13	T21	T4	T12	T20					
B	NC2	T6	T14	NC1	T5	T13	T21					
C	PC1	T7	T15	NC2	T6	T14						
D	PC2	T8	T16	PC1	T7	T15						
E	T1	T9	T17	PC2	T8	T16						
F	T2	T10	T18	T1	T9	T17						
G	T3	T11	T19	T2	T10	T18						
H	T4	T12	T20	T3	T11	T19						

Assays: 1-4 Assay1  
4-7 Assay2

Figure 5-10: Two Assays on a plate (start assay after previous assay)

### Layout Optimization

However, starting each assay on a new strip means you may have unused wells on a test plate, as in the example above where only one well is used respectively on Strip 4 and Strip 8. This means that you will "lose" the seven unused wells located on each of these strips. In that case, it may be worth it to decide to test sample T21 (for each assay) in a later run.

See chapter 5.3.1 on page 5-15 to remove sample T21 from the worklist/plate.

Plate 1												
	1	2	3	4	5	6	7	8	9	10	11	12
A	NC1	T5	T13	NC1	T5	T13						
B	NC2	T6	T14	NC2	T6	T14						
C	PC1	T7	T15	PC1	T7	T15						
D	PC2	T8	T16	PC2	T8	T16						
E	T1	T9	T17	T1	T9	T17						
F	T2	T10	T18	T2	T10	T18						
G	T3	T11	T19	T3	T11	T19						
H	T4	T12	T20	T4	T12	T20						

Assays:	1-3	Assay1
	4-6	Assay2

Figure 5-11: Two Assays on a plate (without sample T21)

You now have an optimized layout and you can prepare your microplate accordingly.

#### 5.3.3.5 Results

If you process several assays on the same plate, the system will still generate only one result file per plate. The results corresponding to each assay will be displayed in this file one after the other, with the same order that they had on the plate (i.e. full results for Assay 1, then full results for Assay 2...).

### 5.3.4 Save or Open a Worklist

If you generally use the **Elisys Duo** system for the same assays or for repetitive jobs, you can shorten the worklist creation process by reusing previously defined (and saved) worklists (also called panels).



---

*When a worklist is saved, the system stores only the plate and assay arrangements but not the Patient IDs. This is because it is assumed that if the worklist file is used again in a new worklist and for a new test run, it will normally be for a new set of samples. This is why, even if you use an existing worklist file to create a new worklist, you have to redo the Add patient step.*

---

#### Save Worklist

1. Create a worklist with your plate and assay arrangement.
2. In the Worklist window:
  - For new or changed worklists:  
Click on the **Save** button or select the **File > Save Panel** menu item.
  - For changed worklists with changed file name:  
Select the **File > Save Panel as** menu item.
3. Enter the file name and save the worklist (see chapter 3.4 on page 3-14).

Worklist files have a (\*.wor) extension. By default, they are saved in the default directory (see chapter 7.1.6.1 on page 7-9).

#### Load Worklist

1. Click on the **Open** button.
2. Click on the **Worklist Files (\*.wor)** symbol.
3. Select your desired worklist file and load it (see chapter 3.3 on page 3-11).
4. Select patient(s) for the plates.
5. Start the worklist.

## 5.4 Worklist Options



### *Required access rights: Edit Worklist Options*

After a worklist has been prepared and before it is started it is possible to check and/or edit the worklist processing options. By default, the system uses the previously defined worklist options. Some options are locked and cannot be changed even by supervisors (users with full access rights).

Click on the **Edit Options** button or select the **Edit > Panel Options** menu item to invoke the **Worklist Options** dialog.

The **Worklist Options** dialog will shown with several registers:

- **Scheduling** (see chapter 5.4.1 on page 5-24)
- **Before** worklist will be started (see chapter 5.4.2 on page 5-27)
- **During** worklist is running (see chapter 5.4.3 on page 5-29)
- **After** worklist was finished (see chapter 5.4.4 on page 5-31)

### 5.4.1 Worklist Options: Scheduling

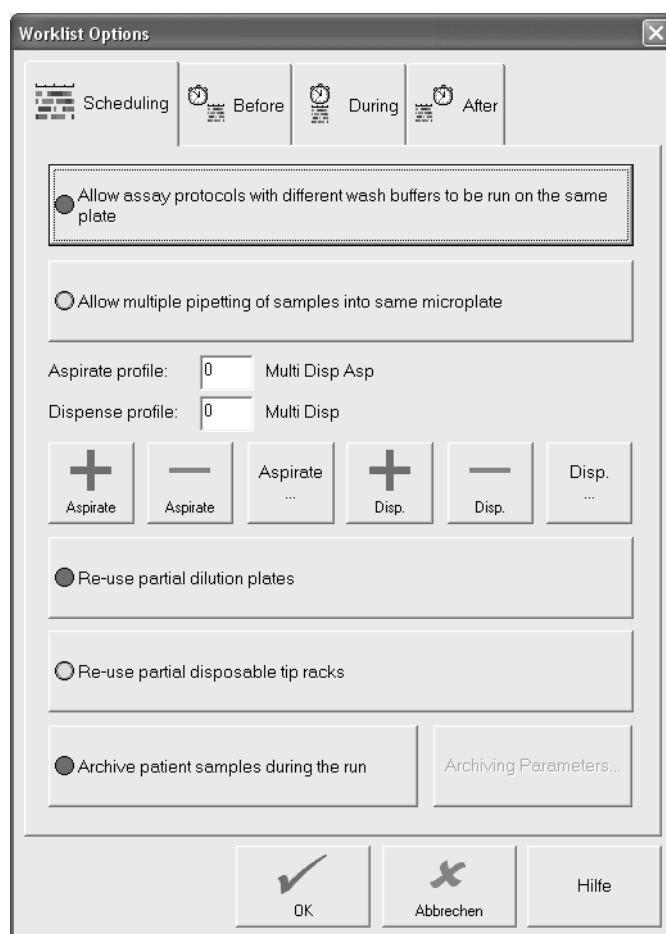


Figure 5-12: Worklist Options dialog - register Scheduling

Function	Description
Allow assay protocols with different wash buffers to be run on the same plate	Worklist definitions are permitted where different wash buffers are being used. This option is always checked and may not be unchecked (even by users with supervisor status).
Allow multi pipetting of samples into same microplate	<p>If a sample is to be pipetted into more than one well on a plate, this option allows to pipette this sample with only one tip into all wells required together.</p> <p>Risk: Drift constraints!</p> <p>See note below!</p>
Archive Parameters	Not used
Archive patient samples during the run	Not used
Aspirate profile	<p>Only used for multipipetting:</p> <p>Select the desired aspirate profile. The aspirate profile you define here will apply to both samples and reagents (controls, standards or diluents).</p>
Aspirate +	Shows next aspirate profile.
Aspirate -	Shows previous aspirate profile.
Aspirate	Shows the selection dialog with all aspirate profiles.
Dispense profile	<p>Only used for multipipetting:</p> <p>Select the desired dispense profile. The dispense profile you define here will apply to both samples and reagents (controls, standards, diluents).</p>
Disp. +	Shows next dispense profile.
Disp. -	Shows previous dispense profile.
Disp.	Shows the selection dialog with all dispense profiles.
Re-use partial disposable tip racks	Partially used tip racks are registered and re-used for later worklists. See chapter 4.7.6 on page 4-42 on when to select this option or not.

Table 5-9: Functions of the Worklist Options dialog - register Scheduling

#### Multi Pipetting



---

*Do not use the multi pipetting function, if you use assays where the functions Eliminate assay drift caused by this operation (pipette or dispense step) or Time incubation from start to previous assay step (incubate step) are enabled (see "Assay Programming Manual")!*

---

Note that if this option has been selected, samples that are pipetted in parallel within the plate are pipetted before all other samples on the same plate.

This makes this option strictly incompatible with all assays that include the "assay drift compensation" feature (see "Assay Programming Manual").

This can also create unsuitable pipetting sequences when:

- only some samples are assigned to both tests.
- or, the multiple determination option (see chapter 5.3.2 on page 5-19) has been used for some or all samples.
- or, the assays include a predilution step.
- or, the order in which the controls have to be dispensed (i.e. strictly before or strictly after the samples) must not be changed.

If in doubt, do not select this option or call your application engineer for assistance.

## 5.4.2 Worklist Options: Before Worklist will be started

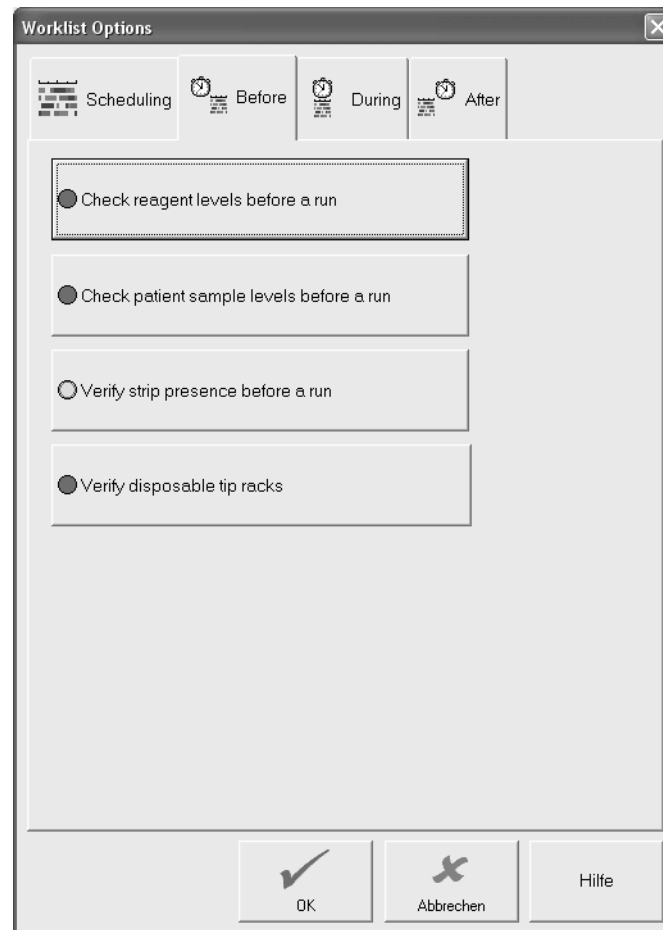


Figure 5-13: Functions of the Worklist Options dialog - register Before

Function	Description
Check patient sample levels before a run	See chapter 4.8.1.3 on page 4-51
Check reagent levels before a run	See chapter 4.8.1.2 on page 4-50.
Verify disposable tip racks	When starting to process the worklist, the system checks the size of the first tip of each rack to make sure the racks have been loaded as displayed in the Load dialog box (i.e. long tips and short tips have not been mixed up). See chapter 4.8.1.4 on page 4-52.
Verify strip presence before a run	<p>Each time a test plate is loaded, it is first moved into the photometer so that the system can check that it includes the correct number of strips. This is useful especially when using plates with removable strips. This item is checked by default and may not be unchecked (even by users with supervisor status).</p> <p><b>Note:</b> This function should always be activated to avoid wrong results, contaminations or damages.</p>

Table 5-10: Functions of the Worklist Options dialog - register Before



### 5.4.3 Worklist Options: During Worklist is running

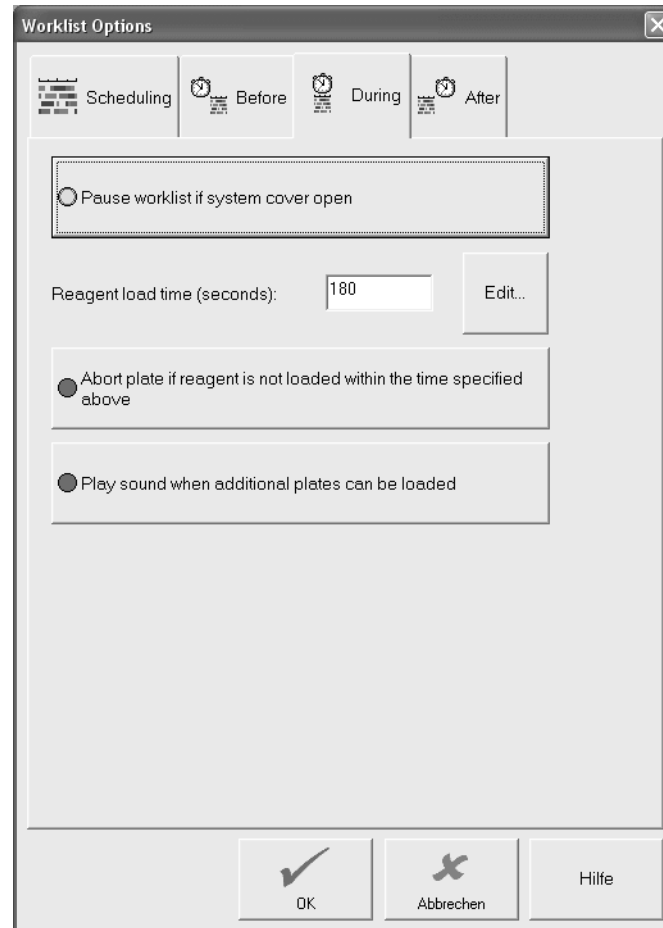


Figure 5-14: Functions of the Worklist Options dialog - register During

Function	Description
Abort plate if reagent is not loaded within the time specified above	Aborts the respective plate processing if the reagent is not loaded within the time specified above. Check this item if you intend to use <b>Elisys Duo</b> as a "walk away" system (e.g. at night). That way, the respective plate will be aborted but the rest of the run will continue.
Pause worklist if system cover open	Stops the instrument immediately when the instrument cover has been opened. This item is checked by default and may not be unchecked (even by users with supervisor status).
Play sound when additional plates can be loaded	An acoustic signal will warn the operator when additional plates can be loaded to a running worklist. This item applies to Continuous Loading (see chapter 5.6 on page 5-44) and is generally checked.
Reagent load time	Enter the maximum reagent load time in seconds. This applies when unstable reagents have to be loaded while a worklist is being processed (see chapter 4.7.4 on page 4-39). The system will warn the operator beforehand (warning message in the software and acoustic signal) and pause the system during the specified load time. This load time should be long enough to allow correct loading but not so long as to affect the processing of the run.  Recommended time is 180 seconds (3 minutes). Entries between 0 and 1000 are acceptable.

Table 5-11: Functions of the Worklist Options dialog - register During

#### 5.4.4 Worklist Options: After Worklist was finished

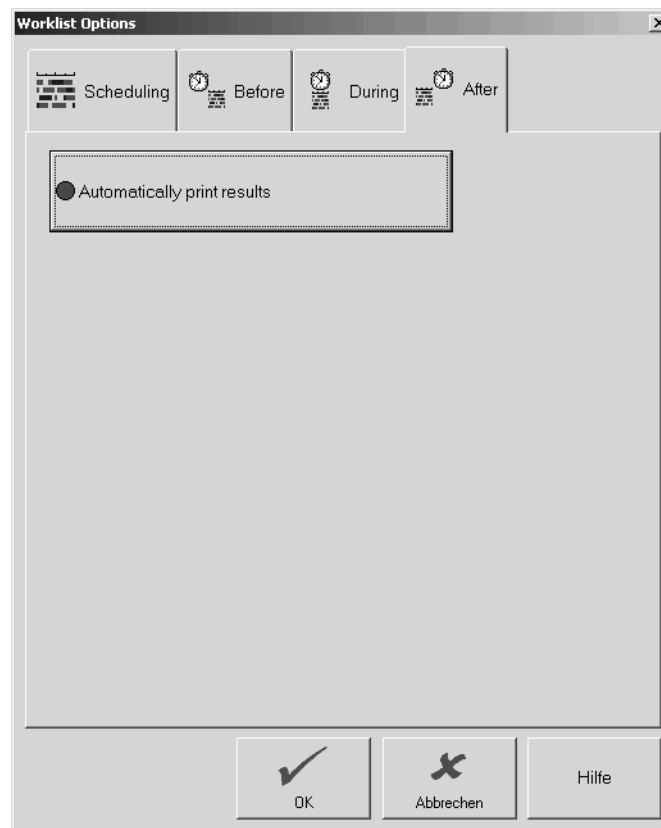


Figure 5-15: Functions of the Worklist Options dialog - register After

Function	Description
Automatically print results	Check this option if you want the system to print the result file as soon as it is generated, i.e. as soon as the processing of the respective plate is over.

Table 5-12: Functions of the Worklist Options dialog - register After

## 5.5 Advanced Options

### 5.5.1 Optimize the Schedule

When you have finished defining your worklist (in the **Set-Up Panel** dialog) and your worklist options (see chapter 5.4 on page 5-24), the **Elisys Duo** software calculates the best way to combine the various steps of each process, while maintaining the plate processing sequence you defined.

If you want to try and optimize this process even further by changing the order in which the various plate are going to be processed:

1. Select the **Edit > Optimize** menu item. The system tries all possible plate orders and automatically reschedules the run using the plate order with the shortest overall processing time.



---

*For very complex worklists, the optimization process may take a long time while the system calculates all possible combinations. If no solution has been reached within a few minutes, it is recommended to abort the process (click on the **Abort** button in the **Optimizing** dialog) and reschedule the worklist manually if necessary.*

---

If you want to optimize the processing manually:

1. Go back to the **Set-Up Panel** dialog by selecting the **Edit > Panel Definition** menu item.
2. Edit the worklist by highlighting the elements you want to change and using the **Edit**, **Delete**, **Move Up**/**Move Down** buttons (see chapter 5.3.1 on page 5-15 for more information on these buttons).
3. Click on the **OK** button.

#### Planning a Daily Workload

Optimizing the schedule is particularly important if you want to process a large number of samples in a minimum time (e.g. processing 500 samples with several assays and within an 8-hour work shift). In such cases, determining the best schedule may require you to try out many different solutions (Some assays are easier to combine than others. Sometimes it is better to do two runs. Sometimes you want to avoid operator intervention at a certain time of day, etc.). If finding the right schedule is not obvious, you can use the **Demo Mode** (see chapter 5.10 on page 5-54) to do all your planning/optimizing and to simulate the various possibilities.

## 5.5.2 Advanced Load Options

### 5.5.2.1 Save/Open Reagent Layout

If you are using non-bar coded reagent bottles and if you are generally repeating the same tests over and over, you may try to shorten the reagent allocation process by using the Save Reagent Layout and Open Reagent Layout function.



---

---

***The system will not check opened reagent layouts. Make sure that positions are correct!***

---

---

#### Save

##### To do this:

1. The first time you use the desired worklist, load the reagents on the instrument and allocate them manually in the Load dialog as described in chapter 5.5.2.3 on page 5-37.
2. Click on the **Save Reagent Layout** button.
3. After clicking on the function, the **Save** dialog is opened (see chapter 3.4 on page 3-14). Enter an appropriate file name and save the reagent layout. (Reagent layout files have a (\*.rea) extension.)

#### Open

##### To do this:

1. The next time you want to process exactly the same tests with the same reagents (and new samples of course), in the Load dialog, click on the **Open Reagent Layout** button.
2. In the **Open** dialog (see chapter 3.3 on page 3-11) which is then displayed, select the desired (\*.rea) file and open it.  
All the reagents are automatically allocated. Now fit the reagent bottles in the racks making sure you **reproduce exactly the layout which is displayed in the Load dialog**.



---

*If you intend to use this function on a standard basis, include small labels on the rack itself or copy and fill in the rack layout forms in order to keep a "reference picture" of each saved layout.*

---

5.5.2.2 Scanner Configuration

Sample Rack  
Tab

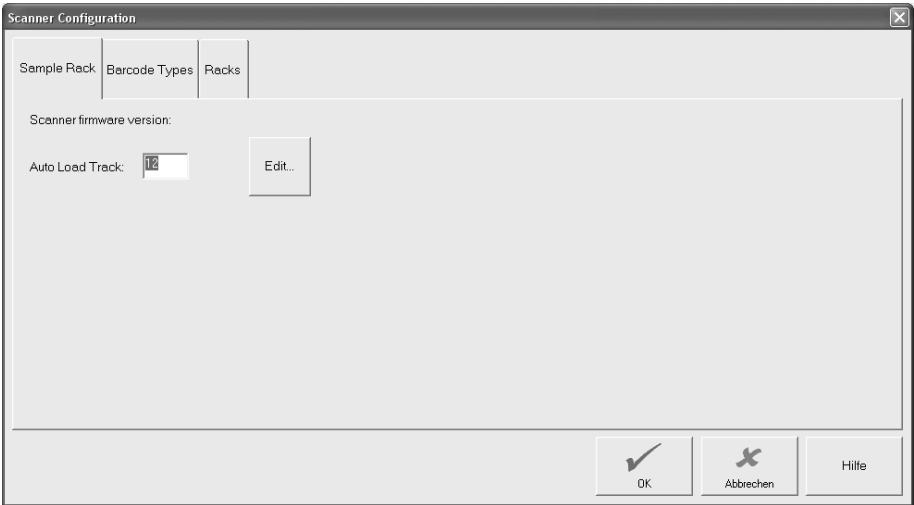


Figure 5-16: Scanner Configuration dialog: Sample Rack tab

Function	Description
Auto Load Track	Enter the first line to be loaded. See also chapter 9.2.1.8 on page 9-17.

Table 5-13: Functions of the Sample Rack tab



*Do not use the Prefix /Suffix fields to exclude a Checksum.*



*If you intend to make use of the Checksum and/or the Prefix /Suffix options, it is essential that you label empty tubes and validate your settings on these before running actual sample tubes. Check in particular that the Sample IDs read by the bar code scanner and the Sample IDs in the result report correspond to what you expected.*

## Barcodes Types Tab

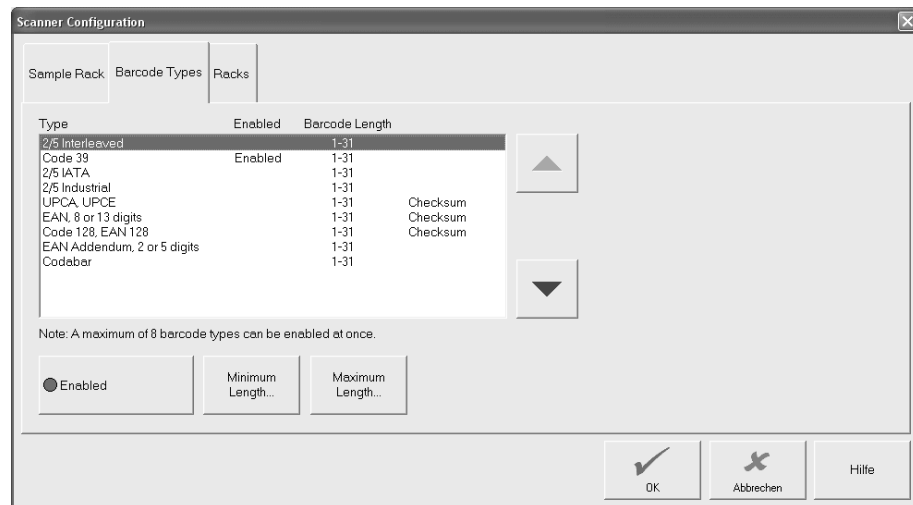


Figure 5-17: Scanner Configuration *dialog*: Barcodes Type *tab*

Function	Description
List	<p>List of all bar code types that can be read by the integrated bar code scanner. If a checkbox is selected, the scanner is able to read the respective bar code type. It is possible to select several checkboxes but the more checkboxes are selected, the slower and less accurate the reading will be.</p> <p>Some bar codes types are always selected and cannot be unchecked (bar code types used on <b>Elisys Duo</b> racks and reagents).</p> <p>The following bar code types can be used for samples and reagents to be processed on the <b>Elisys Duo</b> system:</p> <ul style="list-style-type: none"> <li>• 2/5 Interleaved,</li> <li>• Code 39,</li> <li>• 2/5 IATA,</li> <li>• 2/5 Industrial,</li> <li>• UPCA, UPCE,</li> <li>• EAN 8 or 13 digits,</li> <li>• Code 128, EAN 128,</li> <li>• EAN Addendum, 2or 5 digits,</li> <li>• Codabar.</li> </ul> <p>Typically, when the system is installed, your service engineer configures the bar code scanner to accept the bar code types you generally use on the samples you process.</p> <p>If you later need to change the preconfigured bar code settings, see chapter 7.2.5.1 on page 7-27.</p>
Enabled	Enables a bar code type in the list.
Minimum Length + Maximum Length	<p>Minimum and maximum character length of each bar code type.</p> <p><b>Note:</b> Generally, if you do not know these values, you can leave the default values. However, if you also use the <b>Bar-code Prefix</b> and <b>Barcode Suffix</b> options to exclude some digits, you should enter in the <b>Minimum Length</b> and <b>Maximum Length</b> fields exactly the number of significant digits (including the prefix and suffix) in the respective bar code type. For example, if you use a bar code format with 14 digits altogether and exclude the date suffix (6 digits), enter "14" in both the <b>Minimum Length</b> and <b>Maximum Length</b> fields.</p> <p><b>Note:</b> Wrong settings could lead to false bar code values.</p> <p>Example:</p> <ul style="list-style-type: none"> <li>• Max. = 6</li> <li>• Bar code 1: 2007P45</li> <li>• Bar code 2: 2007P48</li> <li>• Result: 2007P4 for both bar codes!</li> </ul>

Table 5-14: Functions of the Barcodes Type tab



**If you change the bar code settings (e. g. length, checksum) it is necessary to validate this settings with your bar codes.**



## Racks Tab

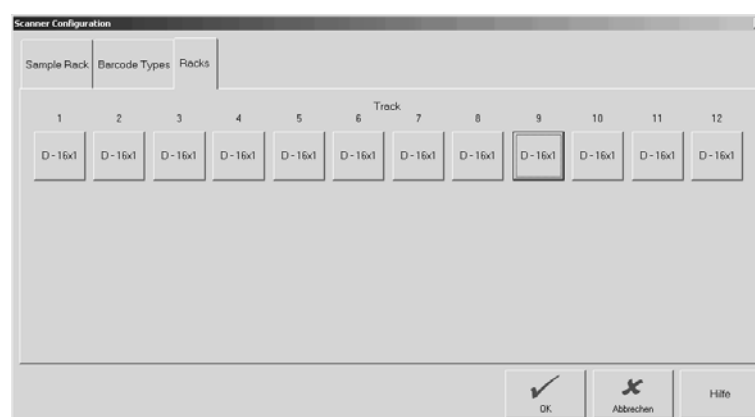


Figure 5-18: Scanner Configuration dialog: Racks tab

Function	Description
Racks	<p>If a rack is identified through bar codes, the rack type is automatically displayed. If identification via bar codes was not possible (damaged or dirty bar codes), you have to select the rack type manually.</p> <p>With three-track racks the same rack type must occupy the respective tracks.</p>

Table 5-15: Functions of the Racks tab

### 5.5.2.3 Allocate Non-bar Coded Racks and Samples

If you are using non-bar coded racks (or racks with damaged or dirty bar codes), the central section of the Load dialog is empty when it opens:

1. Click on the **Scanner Setup** button at the bottom of the Load window. This will open the **Sample Rack** tab in the **Scanner configuration** dialog (see chapter 5.5.2.2 on page 5-34).
2. In the **Rack** tab, use the lane buttons to specify which type of rack you have loaded or intend to load on which track.
3. Confirm with **OK**.



*Make sure that the position to which the system or the user allocate a sample on the screen corresponds exactly to the real position of the corresponding sample tube in the rack! This is very important as wrong allocation is equivalent to mixing up samples.*

Now the racks are depicted as empty (rows of blank dots) in the rack system area of the Load dialog. The required samples are depicted as **Unallocated** resources. Allocate the samples as described in chapter 4.7.2.2 on page 4-34.

Replacement bar code labels for sample racks can be ordered.

### 5.5.3 Test Plate Removal



*It is not necessary to use this function (see chapter 4.8.7 on page 4-57).*

If you notice a serious problem on one plate while the run is being processed, you can use a special procedure to remove this plate from the instrument.

This is an emergency procedure only. It should not be used on a standard basis. Removing the plate may affect the results.

**To remove the plate:**

1. From the Worklist window, select **System Utilities** in the **Utilities** menu. The **System Utilities** dialog is displayed.

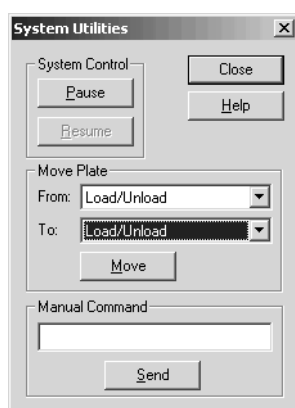


Figure 5-19: System Utilities dialog

2. In the **System Control** field, click on the **Pause** button.
3. In the **Move Plate** field, use the two drop-down lists to specify how to move the plate.
  - In the **From** field, select the present location (washer, photometer, incubator, pipetting area...) of the plate you want to remove from the system.
  - In the **To** field, select **Load/Unload** so that the plate transport unit brings the plate to its unloading position.
4. Click on the **Move** button.
5. In the **System Control** field, click on the **Resume** button.
6. Close the **System Utilities** dialog with the **Close** button.

If you are able to correct the problem rapidly enough and you think it is worth reloading this plate and processing it further:

1. From the Worklist window, select **System Utilities** in the **Utilities** menu. The **System Utilities** dialog is displayed.
2. In the **System Control** field, click on the **Pause** button.
3. In the **Move Plate** field, use the two drop-down lists to specify how to move the plate.
  - In the **From** field, select **Load/Unload**.
  - In the **To** field, select the module where the transport unit should move the plate to resume its processing (if you did not close the **System Utilities** dialog after unloading the plate, the **From** and **To**

fields should already be correctly set - by default, the system reverses the locations selected when unloading the plate).

4. Click on the **Move** button.
5. In the **System Control** field, click on the **Resume** button.
6. Close the **System Utilities** dialog with the **Close** button.

## 5.5.4 Editing/Recalculating the Results

If you think the results are not entirely satisfactory, the **Elisys Duo** software allows you to edit and/or recalculate them before saving, printing or exporting them.

To edit the results, select one of the following functions:

- Outliers
- Parameters/Lot Specific Values
- Assays

These items are enabled only when a result file is open.

### 5.5.4.1 Editing Outliers



*Required access rights: Manually remove outliers*

The **Outliers** function allows you to manually remove from the results some OD values which you think are not consistent with the test (e.g. if some samples were not properly treated or processed) and should not be taken into account when calculating the results.

**Outliers**

Assay Protocol: Assay Demo 1      Reading: #1 - 450/690      Data Set: 1

	1	2	3	4	5	6	7	8	9	10	11	12
A		1,137										
B	1,133	X										
C	1,135	X										
D	1,146	1,145										
E	1,133	1,142										
F	1,134	1,140										
G	1,137	1,144										
H	1,136	1,134										

Statistics  
Label:      Mean:      SD:      CV:      SE:

Ctrl    Shift    Undo    Redo    OK    Cancel    Help

Figure 5-20: Outliers dialog

Function	Description
Assay Protocol	Opens a dialog to change the used assay for the plate. After the change, the Outliers dialog shows the used wells for the selected assay.
Reading	The Reading button shows the filter(s) used for the reading.
Data Set	Not used
Select All	Selects all wells of the plate.
Remove	Marks the selected well as outlier.
Restore	Remove the outlier mark.

Table 5-16: Functions of the Outliers dialog

You cannot edit the values but only remove them. A removed value is displayed crossed out. Conversely, if a value was removed from the calculation automatically by the software (for example, because of bad pipetting or dispense verification errors), you can choose to restore it.

#### Use:

1. Click on the Outliers button in the Result window.
2. Even if you belong to a user group authorized to edit outliers, the Log On dialog (see chapter 4.2 on page 4-3) will be displayed again and you will have to log yourself on again before you can access the Outliers dialog.
3. Remove all outliers (see table 5-16 on page 5-41).
4. Click on the OK button.  
The new result report includes the following comment: "Removed wells: ..."
5. Click on the Recalculate button to recalculate the results taking into account the changes you made.  
The new result report includes the following comment: "WARNING! Results have not been processed using the original assay."

## Recalculating flagged Results

The Restore button of the Outliers dialog can be used to force the system to calculate results for flagged samples that have automatically been removed from result calculation (e. g. if you opened the instrument cover during a run but still want to know the results for those samples pipetted after you opened / closed the cover).



*This possibility can only be used for samples with the following flags: SpIRem (Sample rack removed), CovOp (Cover open), VCFail (Validation criteria failure) or IncKo (Incubation overrun).*

#### To do so:

1. In the original Result Report, display the Combined Report part.
2. Check the flagged samples.
3. If you want to recalculate some of these flagged samples, note their locations on the plate (layout labels).
4. Open the Outliers dialog and restore the corresponding wells (layout labels) as described above.

5. Recalculate the Result Report as described above.  
In the recalculated Result Report, the selected flagged results are now calculated but the original flags remain. **It is the user's responsibility to check and validate such recalculated results.**

#### 5.5.4.2 Changing the Lot Specific Parameters



The Parameters function (Lot Specific Values button) opens the Lot Specific Values dialog (see chapter 4.5 on page 4-11), showing the data of the reagents used for each assay. This lets you correct possibly incomplete lot data or edit some parameters.

When you click OK, the results are recalculated taking into account the changes you made. The new result report includes the following comment: "WARNING! Results have not been processed using the original assay."

#### 5.5.4.3 Recalculation with another Assay

The Assays button opens the Change Assay Protocol dialog.

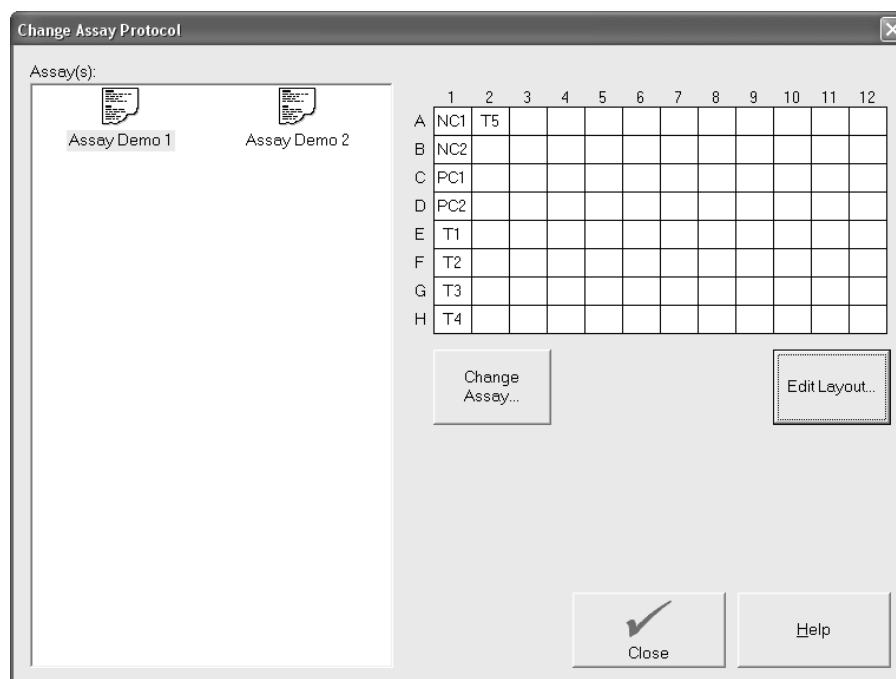


Figure 5-21: Change Assay Protocol dialog

Function	Description
Assay(s)	Shows all used assay for the plate. After the change, the <b>Change Assay Protocol</b> dialog shows the used wells for the selected assay.
Change	Opens a dialog to change the used assay for the plate. After the change, the <b>Change Assay Protocol</b> dialog shows the labels of the used wells for the selected assay.
Edit Layout	This function opens the <b>Assay Layout</b> dialog (see chapter 5.3.1.1 on page 5-17).

Table 5-17: Functions of the Change Assay Protocol dialog

This function allows you to recalculate the results with another assay protocol while retaining the original OD values of your plate. This can be useful, for instance, if you have several versions of the same assay, all with the same processing steps but with different evaluation steps or validation criteria.

1. Click on the **Assays** button in the Result window.
2. Click on the **Change** button and change the assay protocol.
3. Click on the **Close** button.

When you click the **Close** button in the **Change Assay Protocol** dialog, the results are recalculated. The new result report includes the following comment: "WARNING! Results have not been processed using the original assay."

#### 5.5.4.4 Recalculating the Results

A recalculation of the results is performed automatically each time you use some of the editing functions described above.

But the **Elisys Duo** software also allows you recalculate results independently from the above editing operations.

##### To do so:

1. Click on the **Recalculate** button in the Result window.  
The new result report includes the following comment: "WARNING! Results have not been processed using the original assay."

This function is useful if you are editing or defining an assay. If you change the assay evaluation parameters and recalculate, the data reduction of the raw data will be done using the new parameters (you need to save your assay changes before recalculating).

## 5.6 Continuous Loading



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*Required access rights: Edit running Worklists*

---

Continuous loading is the process by which new samples and new test plates are inserted into the instrument while the instrument is running a worklist. The **Elisys Duo** system allows this but only at certain times and under specific conditions.

The main advantage of continuous loading is that it allows the user to test more samples and/or to use more than 3 test plates in a single test run.



---

*An absolute maximum of 3 plates can be in the instrument at the same time. If you want to process more than three plates in the same run, you will first have to unload completely processed plates (the system will prompt you to do so).*

---

### **Change of worklist options during continuous loading:**

The only worklist option (see chapter 5.4 on page 5-24) that cannot be changed during continuous loading is the **Reagent load time** (which is greyed out). But any changes that are made are only applied to the new plates. So, the already loaded plates will continue to use whatever multi pipetting mode was in force at the time that they were scheduled.



### 5.6.1 Check Reloading Time(s)

The first thing to do if you intend to add new samples and new plates to an already running worklist is to check when this will be possible.

Reloading sample racks can be done at any time as soon as a red LED opposite an already loaded sample rack is flashing. But the actual reloading process, in which the system recalculates the worklist and directs the operator to load (and allocate) the other required resources and the test plates, and unlocks the instrument accordingly, this can only be done when the pipettor is not busy. The only time this is allowed is when all the plates on the current worklist are incubating.

#### To check the reloading intervals:

1. In the Worklist window of the **running** worklist, click on the **Schedule** button (see chapter 4.6.2 on page 4-17).

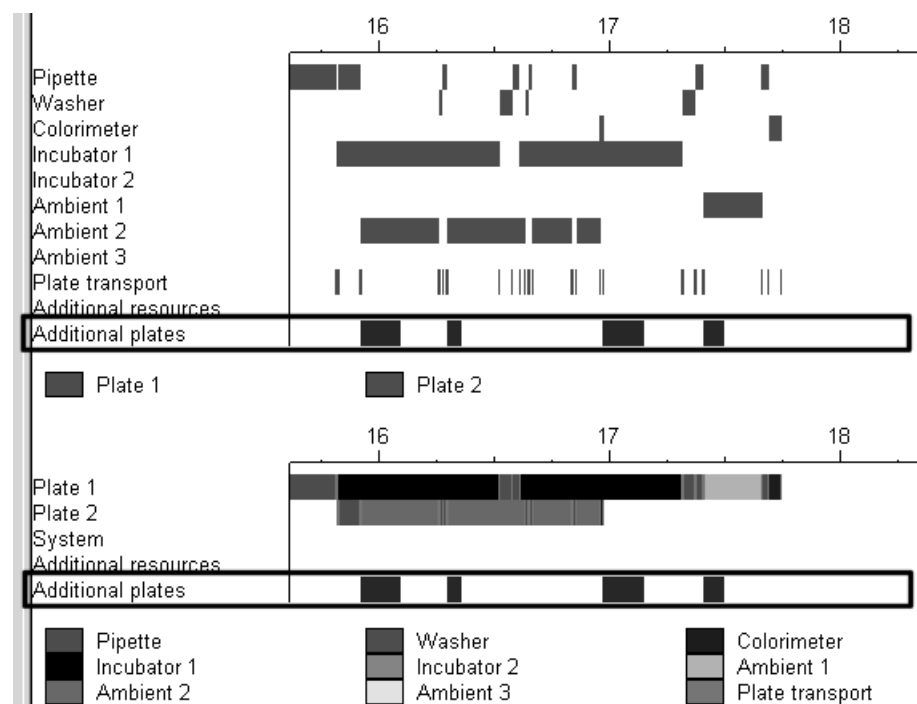


Figure 5-22: Schedule (example)

2. In the **Additional Plates** line, the brown sections indicate the time intervals when reloading will be possible. This line is seen both in the module view and in the plate schedule view.

The more complex your current worklist, the more restrictive the available reloading intervals will be.

## 5.6.2 Preparing and Loading the New Samples

1. Place your new samples in sample racks. If you are using bar coded sample tubes, make sure the bar code labels face right so that they can be scanned by the bar code reader when the rack is inserted.
2. As soon as a red LED opposite a sample rack is flashing, you can remove the respective rack (the flashing red LED indicates that the pipetting is over for this rack) and load the rack with your new samples.
3. Repeat this step if you are loading more than one additional sample rack.
4. The system will display the tabular **Patient Editor** dialog (see chapter 4.3.1 on page 4-5). If the samples were bar coded, the patient IDs are already entered in the first column. If samples were not bar coded or the bar codes could not be read, you have to enter the patient IDs manually.
5. Using the drop-down lists, select the appropriate assays and assign them by checking the corresponding lines (see chapter 4.3.1 on page 4-5).
6. Click on the **Close** button. If you reload more than one new sample rack, the system will display the tabular **Patient Editor** dialog again for each rack.

For this step, you do not need to wait until all the currently loaded plates are incubating. Therefore:

- Make sure all your sample racks are ready before you remove it.

## 5.6.3 Redefining the Worklist

Once you have loaded the additional sample racks and assigned assays in the **Patient Editor** dialog boxes as described above, the system automatically reschedules the current worklist to include the additional plates.

If the additional samples you loaded correspond to samples included in test orders downloaded from the LIS, assays are already assigned in the successive **Patient Editor** dialog boxes and you just need to close these dialog boxes by clicking the **Close** button.

You now need to confirm the automatically redefined worklist and specify the reagent lots for the additional tests.

To do so:

1. Click on the **Edit Panel** button. This opens the **Set-up Panel** dialog (see chapter 4.4 on page 4-10). In the left-hand side window, you can see the new plates that have been automatically added to the worklist.



*By default, when the systems reschedules the worklist to include the additional samples you have loaded it systematically tries to combine several assays on each plate (provided these assays have compatible processing parameters).*

---

2. If you are satisfied with the automatically redefined worklist, click on the **OK** button to close the **Set-up Panel** dialog. If not, edit the worklist and then click on the **OK** button. The **Lot Specification** dialog is displayed for the first additional plate.
3. Identify the lot numbers and expiration data for all assay kits and assay components for this plate and all additional plates and click on the **OK** button.

### 5.6.4 Reloading other Resources

After you have clicked on the **OK** button in the **Lot Specific Values** dialog, the system checks its current status:

- If it is currently going through an incubation phase (for all plates), reloading is allowed and the **Load** dialog box appears.

**In that case:**

- Refill or add the resources (reagents, dilution plates, tip racks, wash buffer) required for the additional processing as shown in the **Load** dialog.
- Allocate them as if you were starting a new run. The new samples should already be allocated. If not, allocate them manually if they are not bar coded. If they are bar coded, open the door of the rack unit, withdraw the new racks and insert them again, see chapter 5.6.2 on page 5-46.
- After loading and allocation of all required resources, click on the **OK** button. The **Load Plate** dialog is displayed.
- If the system is currently (or will soon be) performing other steps of the running worklist (e.g. pipetting), a system busy warning message appears.

**In that case:**

- Click on the **OK** button to close the warning message.
- When you reach the allowed reloading time, click on the **Edit Panel** button once more and confirm it with **OK**. The **Load** dialog is displayed.

### 5.6.5 Reloading Test Plates and Further Processing of the Worklist

When the **Load Plate** dialog is displayed:

1. Load the required additional test plate(s) in the same way as done at start of run (as described in chapter 4.7.9 on page 4-46) and confirm with **OK**.



*If some of the plates of the initial worklist are already fully processed when you are ready to reload additional test plates, the system automatically brings them forward to the loading/unloading compartment so that you can remove them before loading the additional plates.*

When you click on the **OK** button in the **Load Plate** dialog, the system recalculates and reschedules the worklist (interlacing or adding new plates/assays to be processed).

Further processing is then carried out in accordance with this new rescheduled worklist.

## 5.7 Patient Result Report



The patient result report shows a compact summary of the patient results of all selected assays.

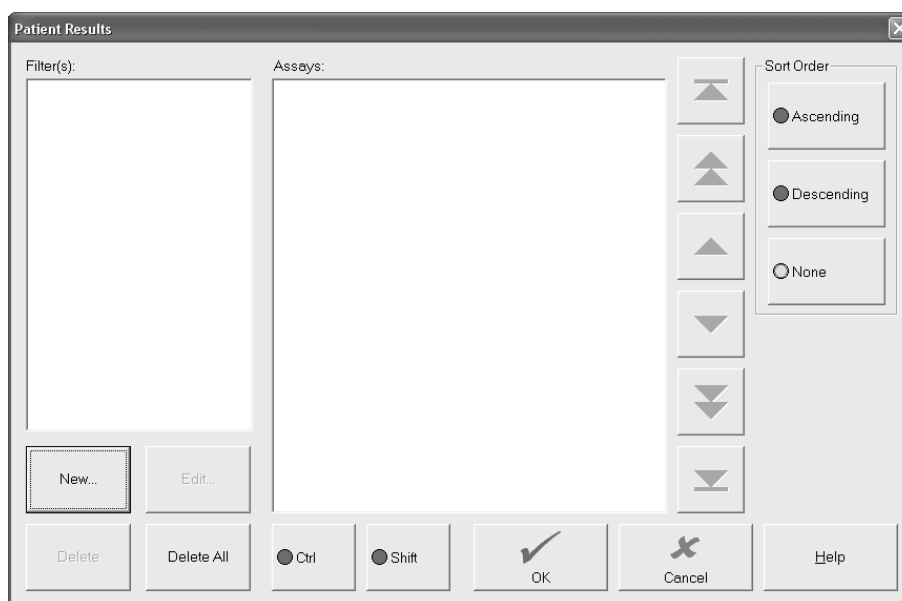


Figure 5-23: Patient Results dialog

Function	Description
Assays	Shows all processed assays.
Delete	Deletes a selected filter.
Delete All	Deletes all filters.
Edit	Allows to edit a selected filter for the patient result report (see chapter 5.7.1 on page 5-51).
Filter(s)	This area shows all existing filters for the patient result report. With a filter, the number of reported patients can be limited. Select a filter to use them. Click on a free position on the area to deselect the filter.
New	Adds a new filter for the patient result report (see chapter 5.7.1 on page 5-51).
Sort Order	The <b>Sort Order</b> field allows you to define the order in which the samples will be shown in the report. Selectable sort order: <ul style="list-style-type: none"> <li>• <b>Ascending:</b> Sorted in alphanumeric ascending order (based on the sample IDs entered or read by the bar code scanner).</li> <li>• <b>Descending:</b> Sorted in alphanumeric descending order (based on the sample IDs entered or read by the bar code scanner).</li> <li>• <b>None:</b> The samples will be shown in the added order.</li> </ul>

Table 5-18: Functions of the Patient Results dialog

**Proceed as follows:**

1. Select the **File > New** menu item.
2. In the **New** dialog, select the **Patient Result Report** symbol. This shows the **Patient Result** dialog.
3. Click on the **New** button to create a filter (e.g. only patient IDs between 0070 and 0100)
4. Select one or more assays.
5. Select the **Sort Order** (see chapter 5.2 on page 5-4).
6. Click on the **OK** button to confirm the entries.  
The system shows you the patient result report.

Patient Results

Signature: \_\_\_\_\_

Patient ID	Assay	Result
0001	CMV IgM	NEG

Patient ID	Assay	Result
0002	CMV IgM	NEG

Patient ID	Assay	Result
0003	CMV IgM	REACTIVE

Patient ID	Assay	Result
0004	CMV IgM	NEG

Patient ID	Assay	Result
0005	CMV IgM	NEG

Patient ID	Assay	Result
0006	CMV IgM	NEG

Patient ID	Assay	Result
0007	CMV IgM	NEG

Patient ID	Assay	Result
0008	CMV IgM	NEG

Patient ID	Assay	Result
------------	-------	--------

Figure 5-24: Patient result report

## 5.7.1 Filter Configuration

With the function you can limited the number of reported patients.

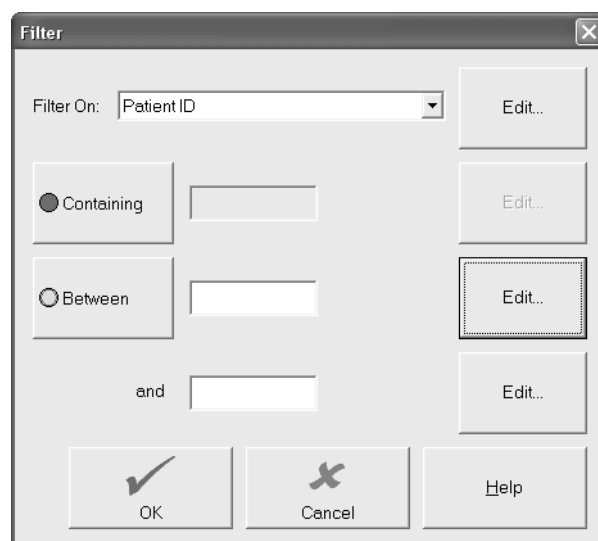


Figure 5-25: Filter dialog

Function	Description
Filter On	Shows the selected filter argument (e.g. Patient ID, Birthdate, Date). Click on the Edit button to change the argument.
Containing	The argument must contain the edited value. Example: <ul style="list-style-type: none"> <li>Filter: Patient ID, Containing: 10</li> <li>Report: Patient 10, Patient 101, Patient 1030, Patient 310, etc.</li> </ul>
Between	The argument must between the edited values. Example: <ul style="list-style-type: none"> <li>Filter: Date, Between: 2008-07-01 and 2008-07-30</li> <li>Report: all tested Patients between 2008-07-01 and 2008-07-30</li> </ul>

Table 5-19: Functions of the Filter dialog

## 5.8 Quality Control Analysis Report (Levey Jennings Plot)



The quality control analysis report (Levey Jennings plot) shows the results of a selected reagent over a period of time.

To generate a QA Analysis Report you have to activate the QA-analysis by defining QA-Labels in the Lot Specific Values (see chapter 4.5 on page 4-11) while preparing a worklist.

### Proceed as follows:

1. Select the File > New menu item.
2. In the New dialog, select the QA Analysis Report symbol.
3. In the Q.A. Analysis dialog, select in the Controls list the respective reagent.
4. Select in the Batch Numbers list the respective batch number.
5. Select the period of time in the boxes Date from and to.
6. Click OK to confirm the entries.

The system shows you the quality control analysis report (Levey Jennings plot).

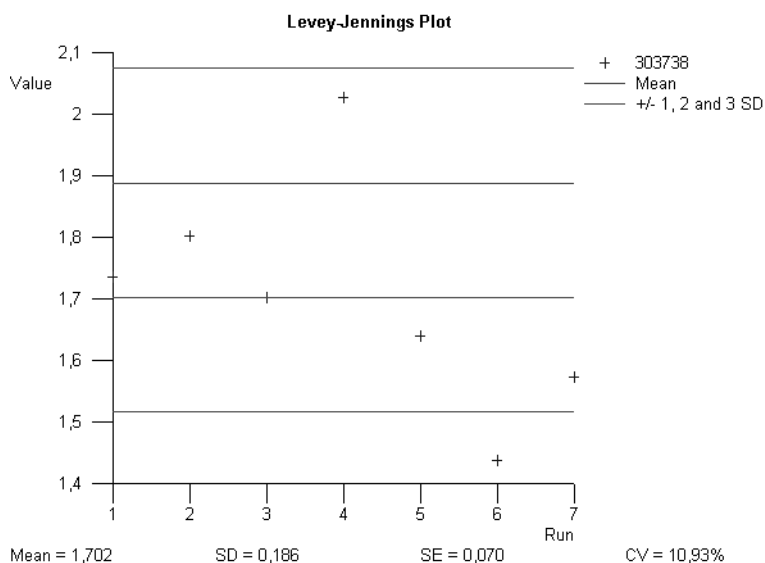


Figure 5-26: Levey Jennings plot



## 5.9 Software Language



---

*Required access rights: Nothing*

---

It is possible to choose the language in which to use the **Elisys Duo** software. This will affect the software layout (menus, dialogs, buttons) but also the documents (assay files, result reports, event logs...) used or generated by the system.

To select the language:

1. Select the **File > Close** menu item to close all open windows (including the selftest report). You should see only the menu bar and toolbar above a gray screen.
2. In the Utilities menu, select the **Select Language** menu item. The **Select Language** dialog is displayed.



*Figure 5-27: Select Language dialog*

3. In the **Select Language** dialog, select one of the available languages from the drop down list.
4. Click on the **OK** button.
5. Close the **Elisys Duo** software and restart it.



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*If you have changed the software language but some elements continue to be displayed in English, this may be because you are using an English-language version of Windows (in this case, some buttons will be in English), or you are using assays that were defined in English.*

---

## 5.10 Simulation Mode / Demo Mode

The simulation/demo mode allows you to work with the **Elisys Duo** software even if no instrument is connected or turned on.

- To do this, check the **Demo Mode** item in the **Log-On** dialog (see chapter 4.2 on page 4-3).

The COM port between the PC and the instrument is then disabled.



---

*Required access rights: The demo mode allows you to access and use all the functions that you would normally use.*

---

You can, for instance, use it to create a worklist and check, on the Schedule view how it would actually be performed on the instrument. The only difference is that the time scale is changed (one minute of a real process is rendered as one second in demo mode) and that no reading values are returned in the results.

You can also use the demo mode to edit the system parameters, edit assays, create panels, access and print former results, etc. Changes made or files created while in demo mode are saved on the system just as they would be normally.

It is therefore a very useful (and safe) mode to use for all operations for which you do not need to use the instrument.

## 6 Connection to a Host Computer

The **Elisys Duo** system has been designed to easily integrate into a laboratory environment. The integrated PC that operates the instrument then has to be also connected to a host computer. This connection enables data to be imported or exported from the host to the **Elisys Duo** system, and back (e.g. download of patient data to the system, upload of test results to the host computer).

For connection, two different methods of exchanging data between the **Elisys Duo** system and a host computer are supported:

- Transfer of ASCII files (import of patient data or worklists into the **Elisys Duo** and export of patient test results to the host computer) - see chapter 6.1 on page 6-2.
- Transfer through an ASTM link (download of test orders to the **Elisys Duo** system and upload of patient results to the host computer) - see chapter 6.2 on page 6-15.

These two methods are described in the following chapters.



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*Note that it is not possible to import absorbance data, pipette data or other file types from other systems or readers.*

---



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*The imported patient ID must be unique! If non-unique patient IDs are used (e.g. same ID for different persons at different worklists), the patient database is incorrect. In this case, features like patient history or patient result report must not be used.*

---



---

*It is necessary to validate the integration in a lab system!*

---



---

*It is necessary to validate the linking of assay names between software and LIS system.*

---

## 6.1 ASCII File Transfer

The **Elisys Duo** has the possibility to import (\*.txt) worklist or patient data files and export (\*.txt) result files from and to a network server.

The import of worklist files can be performed manually by the user or automatically with a polling sequence. Export files are generated and transmitted automatically if this has been defined in the respective assay.

### 6.1.1 Hardware Configurations

The communication between the **Elisys Duo** computer and the host system is established using an Ethernet card.

In case the **Elisys Duo** computer should be connected to another host system, please install the necessary protocol or client and configure it according to the specifications for this host.

**File name restrictions:**

1. For all types of servers, note the following restrictions:
  - File names should not include more than 20 characters.
  - File names should not include special characters except "-" and "\_".
2. Characters allowed in file names are:
  - Numbers from 0 to 9.
  - Letters from A to Z (small and big capitals).

## 6.1.2 Importing Patient Data and Worklist Files (Types of Import Files)

Import files are (\*.txt) files generated by a host computer, which include information about patients and test orders for these patients. The **Elisys Duo** system will be able to import and process these files only if their structure and contents are arranged in a certain order.

### Standard Data Fields:

The standard data fields that can be expected by the **Elisys Duo** system in an import file are: the Patient ID, the Patient Name, the patient's Birthday, the patient's Sex, the Test Name(s) and the Collection Date.

Not all these fields have to be included in the imported files. For instance, you can import worklist files that include only the Patient IDs and the Test Name for each Patient ID (see examples below).

For certain fields, a specific format has to be obeyed (e.g. birth dates must have a YYYYMMDD format, collection dates a YYYYMMDDHHMMSS format).

### Header/No Header:

The **Elisys Duo** system is able to analyse import files with or without header. A file has a header if the first line of the file lists the various data fields included in the file.

### Examples of import files with header:

a)

Patient ID,Test name,Test name,Test name,Test name	Header Row
001,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	Data Fields
002,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
003,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
004,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
005,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
1001,HBs+ Ag,HSV-IgM	
1002,HBs+ Ag,HSV-IgM	
1003,HBs+ Ag,HSV-IgM	

b)

Patient ID,Patient name,Test name,Birth-date,Sex,Collection Date	Header Row
001,David,HBc+ Ab,19690330,,20020330102944	Data Fields
324,Marco,HBs+ Ag,19770119,M,20020330103344	
BF221,Dupont Jean,HIV Ag- Ab,19661101,M,20020330112121	
33SD321,Durand Sophie,HIV Ag- Ab,19770202,F,20020324120229	

Using headers makes it easier if several Test Names are included for each patient. Otherwise, a new line has to be included for each Test Name (see below).

Without a header row, file **a)** above would have to be structured as follows:

001,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	<b>Data Fields</b>
002,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
003,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
004,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
005,HBc+ Ab,HBs+ Ag,HIV Ag-Ab,HCV Ab	
1001,HBs+ Ag,HSV-IgM	
1002,HBs+ Ag,HSV-IgM	
1003,HBs+ Ag,HSV-IgM	

For file **b)**, things would be easier since only one Test Name is included per Patient ID:

001,David,HBc+ Ab,19690330,,20020330102944	<b>Data Fields</b>
324,Marco,HBs+ Ag,19770119,M,20020330103344	
BF221,Dupont Jean,HIV Ag- Ab,19661101,M,20020330112121	
33SD321,Durand Sophie,HIV Ag- Ab,19770202,F,20020324120229	

**Separator:**

The header fields and the data fields are separated by a special character. In the examples above it is a comma (,) but the system lets you specify which character you intend to use as a separator: colon (:), semi-colon (;), vertical bar (|)...

No space should be included between the separator and the data.

Note that if for a given patient all data fields are not filled (e.g. in example b) the birthday of Patient 001 is not known), the data field remains empty but there must still be the same number of separators.

This is true except for the fields at the end of a line (e.g. in example a) for patients 1001, 1002 and 1003 for which only two test are assigned).

**Several tests for patients in one line:**

Example file header row:

...,Test name,Test name, ...

Example file data rows:

...,HBc+ Ab,HBs+ Ag,...

### 6.1.3 Defining Import Parameters

The ASCII Patient Information Import dialog allows the user to "tell" the **Elisys Duo** system what type of import file it is faced with or should expect.

This dialog is displayed each time you import files or when you define your file polling (automatic import) parameters.

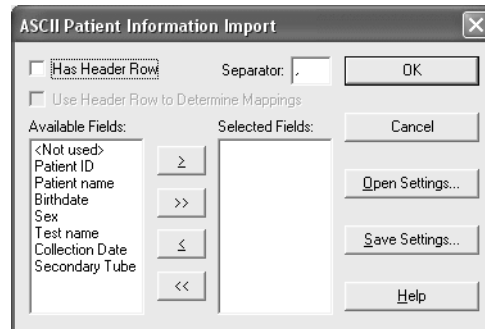


Figure 6-1: ASCII Patient Information Import dialog

Function	Description
Has Header Row	Select this item if the import file has a header. In this case, the next item is enabled.
Use Header Row to Determine Mappings	<p>If you check this item, the system will automatically use the header row to interpret the data fields. In this case, you do not have to specify which data fields are included; the <b>Available Fields</b> list and the <b>Selected Fields</b> list are disabled.</p> <p>If you do not check this item, you are telling the system to disregard the header row and to interpret the data fields according to what you select in the <b>Selected Fields</b> list.</p>
Separator	Enter the character used as separator (see chapter 6.1.2 on page 6-3).
Available Fields	<p>Shows the available fields. Select the fields that the patient ASCII file includes from this list. If you need additional fields, you can load them from a file by clicking on the <b>Open Settings</b> button. This file must include the fields row-wise in the ASCII format. If necessary, you have to create a file with the field names and copy it to the respective subdirectory.</p> <p>See below for field description.</p>
>, >>, <, <<	Use these buttons to transfer data fields from the <b>Available Fields</b> list to the <b>Selected Fields</b> list (or back). You can also transfer fields from one list to the other by double-clicking on them.
Selected Fields	<p>Shows the data fields which the system should expect to find in the import file. Make sure that the order of the data fields in the <b>Selected Fields</b> list is in accordance with the order of the data fields in the import file! You can move a field in the list by selecting it with the mouse and dragging it upwards or downwards without releasing the mouse button.</p> <p>See below for field description.</p>
Open Settings, Save Settings	<p>If the files you import from the host computer always have the same structure and include the same data fields, you do not have to redefine the import parameters each time.</p> <p>Once you have defined the parameters (header row or not, separator, selected data fields), you click on the <b>Save Settings</b> button. This creates a (*.apm) ASCII Patient Information Mappings file which you can re-use for later imports by clicking on the <b>Open Settings</b> button. However, this is useful mainly if your import files do not have header rows that can be used for mappings.</p>

Table 6-1: Functions of the ASCII Patient Information Import dialog



**Field description:**

Field	Description
<Not used>	If there are unused field(s) in the file, you can use this item to hide the unused field(s).
Patient ID	ID number of the patient. Alphanumeric strings accepted.
Patient name	Name of the Patient. No limits on patient name.
Birthdate	YYYYMMDD (year, month, day)
Sex	ASTM states M, F, or U but no actual restrictions
Test name	If you have defined LIS assay names, the software can use these as test names (both in case of manual import and in case of import by file polling).  Otherwise, the imported test name must correspond exactly to the name of the assay file stored in the directory but without the (*.asy) extension.
Collection Date	YYYYMMDDHHMMSS (year, month, day, hour, minutes, seconds)
Secondary Tube	Bar code ID of tube used for sample archiving when sample archiving order is included in the worklist.

Table 6-2: Fields



*After import of all patient information, the file will be deleted automatically!*

### 6.1.3.1 Manual Import of a Patient Information

**To import a worklist file manually:**

1. Select the menu item File > Open.
2. Click on the ASCII Patient Information (\*.exe) entry.
3. Search and select your file.
4. This opens the ASCII Patient Information Import dialog. Define your import parameters as described in chapter 6.1.3 on page 6-5.
5. Click on the OK button to import the patient information.

### 6.1.3.2 Automatic Import (File Polling)

The **Elisys Duo** software allows the user to define specific locations that the software will poll on a regular basis to look for ASCII patient information files. When a valid file is found, it is automatically imported into the software, interpreted and the patient database is updated with the new patient details.

To specify the file polling intervals and the structure of the files to be imported:

1. Select the **Utilities > Options** menu item to open the **Options** dialog.
2. Click on the **Users** tab.

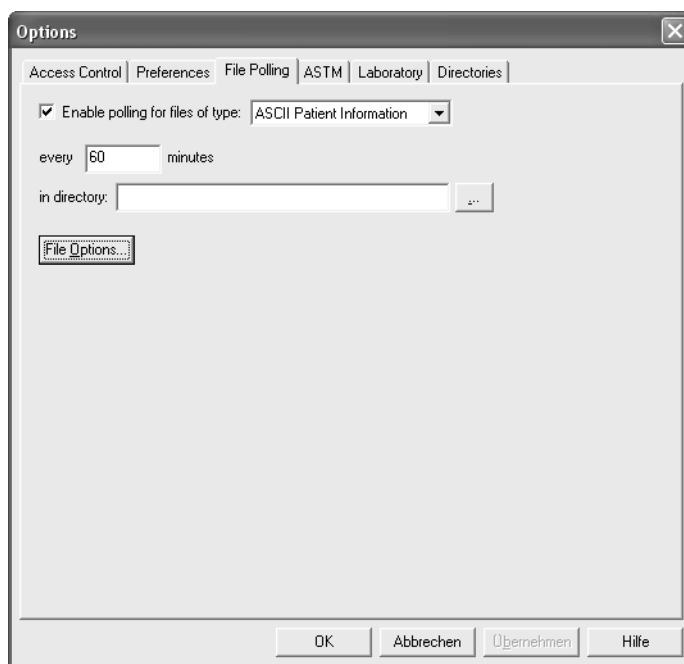


Figure 6-2: Options dialog: File Polling tab

Function:	Description:
Enable polling for files of type	Check this item if the <b>Elisys Duo</b> computer is connected to a host computer. If you select this item, the other boxes on this tab are enabled.  In the drop-down selection list you can select the file type for the patient information. Currently, the only available format is the ASCII format.
every n minutes	Enter the intervals (in minutes) information is to be polled from the host computer.
in directory	Specify the location (directory in the host computer) to be polled. Enter the full path (including a filename). To browse/search, click on the ... button. Find the desired directory and select a file name in that directory.

File Options	Opens the ASCII Patient Information Import dialog and you can enter the structure of the ASCII files to be imported (see chapter 6.1.3 on page 6-5).
--------------	--

3. Activate the **Enable polling for files of type** checkbox.
4. Enter the intervals to request for files.
5. Enter the desired directory.
6. click on the **File Options** button to open the **ASCII Patient Information Import** dialog. Define your import parameters as described in chapter 6.1.3 on page 6-5.
7. Click on the **OK** button twice.



*The system time of the server and the system time of the **Elisys Duo** computer must be synchronized! If the system time of the server is ahead of the system time of the **Elisys Duo** computer and they deviate more than the defined polling time the patient information files will never be imported!*

### 6.1.3.3 Successful Import / Import Failure

If you import a patient data file manually, once you have clicked on the **OK** button in the **ASCII Patient Information Import** dialog, the system displays a succeeded import message.

This message just confirms that the file has been imported. It does not confirm the correct import of all the data fields!

To make sure that all the data included in the file have been successfully and correctly imported into the **Elisys Duo** system, you have to check the **Patient Editor** dialog (see chapter 5.2 on page 5-4). The same method can be used to check if an automatic file polling and import process has been successfully carried out.



*If the patient data that you imported (whether manually or automatically) correspond to samples that you are loading or have loaded on the **Elisys Duo** instrument, the system will automatically display the imported data in the column format **Patient Editor** dialog (see chapter 4.3 on page 4-5).*

### Import Failure

If the patient data was not correctly imported:

- Check that the import parameters that you defined in the **ASCII Patient Information Import** dialog correspond to the actual structure and contents of the file you tried to import.
- Check that the file polling path you specified in the **Options** dialog / **File Polling** tab is correct.
- Check that network communication is not down.
- Check that the system times of the **Elisys Duo** computer and of the host computer are synchronized.

### 6.1.3.4 Deletion of Imported \*.txt Files

To prevent imported worklists from remaining for ever in the import directory, imported \*.txt files are automatically deleted by the system after importing,

(whether by manual import or file polling). Before the file is deleted a copy is made in the Backup folder (see chapter 7.1.6 on page 7-8). The filename of the copy is the same as the filename of the original import file but with a prefix "Copy of", e.g. if the import file is named "worklist4.txt", then the backup copy will be named "copy of worklist4.txt". If the import file always uses the same filename, then the name of the backup copy will be incremented, e.g. "Copy (2) of worklist4.txt", "Copy (3) of worklist4.txt", etc.

#### 6.1.3.5 Importing of Multiple Test Order Requests for the Same Patient

The software uses a registry setting to control what happens when a duplicate test order request is received for the same patient. The registry setting either allows or ignores the duplicate test order request. The default setting is that the duplicate test order request is ignored (and processed as an individual test order). If the duplicate test order request is allowed then, after a successful import, multiple test order requests are shown for the respective patient in the Patient Editor dialog (see chapter 5.2 on page 5-4).

Then, when a worklist is created for this patient a number of wells equal to the number of test order requests will be allocated to the sample. These will be combined by the software and given the same layout label ID (e.g. patient 000001 (x2)).



---

*This only applies when importing from text files. Duplicate ASTM test order requests will always be ignored.*

---

## 6.1.4 Export of Test Results

### 6.1.4.1 Individual Export Requests

Each time a (\*.res) result report is calculated and displayed on the screen, you can decide to export it.

To do so:

1. Select the **Utilities > Export Results** menu item.

If the **Utilities > Export Results** menu item is disabled, it means that the **Elisys Duo** software has already been configured to automatically export the results as described below.

### 6.1.4.2 Automatic Export

See chapter 7.1.2 on page 7-3.

6.1.4.3            Contents of ASCII Export Files

The structure and contents of the ASCII export files depend on what has been defined for each assay (see "Assay Programming Manual").

Examples of  
ASCII Export  
Files

Export file without header field:

<pre>[HBsAg]  [Results] Patient ID Assay Reader value Qual. value " "   "HBsAg"   "0.009"   "NC1" " "   " HBsAg"   "0.011"   "NC2" " "   " HBsAg"   "0.093"   "NC3" " "   " HBsAg"   "1.455"   "PC1" " "   " HBsAg"   "1.465"   "PC2" "001"   " HBsAg"   "0.004"   "neg" "002"   " HBsAg"   "0.011"   "neg" "003"   " HBsAg"   "0.011"   "neg" "004"   " HBsAg"   "0.002"   "neg" "005"   " HBsAg"   "0.987"   "pos" "006"   " HBsAg"   "0.009"   "neg" "007 HBsAg"   "0.075"   "equ" "008 HBsAg"   "0.011"   "neg"  [End of Results]</pre>	<p>No header information</p> <p>Data field header Separator is a vertical bar ( )</p>
---	---

Export files with header field:

<pre>[HBsAg] Time:;11:15:00 Date:;27/09/07 OVER limit:;3.000 Operator:;User Wavelengths:;450nm/620nm</pre>	<p>Assay Header Field</p>
--	---------------------------

<pre> -0.01&lt;=NCi&lt;=0.50; -0.01&lt;=0.010&lt;=0.50; -0.01&lt;=0.009&lt;=0.50; -0.01&lt;=0.011&lt;=0.50; -0.01&lt;=0.093&lt;=0.50;Removed Valid(NC)&gt;=2;2&gt;=2 PCi&gt;=0.550; 1.460&gt;=0.55; 1.455&gt;=0.55; 1.465&gt;=0.55; valid(PC)=2;2=2 </pre>	<p><b>Validation Criteria Header Field</b></p>
<pre> If 'Sample&lt;(NC+0.05)*0.9' Then Result:='neg' If 'Sample&gt;=(NC+0.05)*1.1' Then Result:='pos' Default result := equ </pre>	<p><b>Qualitative Header Field</b></p>
<pre> [Results] Patient ID,Assay,Reader value,Qual. value ","HBsAg","0.009","NC1" "," HBsAg","0.011","NC2" "," HBsAg","0.093","NC3" "," HBsAg","1.455","PC1" "," HBsAg","1.465","PC2" "001"," HBsAg","0.004","neg" "002"," HBsAg","0.011","neg" "003"," HBsAg","0.011","neg" "004"," HBsAg","0.002","neg" "005"," HBsAg","0.987","pos" "006"," HBsAg","0.009","neg" "007 HBsAg","0.075","equ" "008 HBsAg","0.011","neg" [End of Results] </pre>	<p><b>Data field header Separator is a comma (,)</b></p>

#### 6.1.4.4 Target Directory for Export Files

Under default settings:

- Result files (\*.res) are saved in the C:\Programme\Human\Results directory.
- Result Export files (\*.txt) are saved in the C:\Programme\Human\Export directory.

To change the directory where export files are to be saved (for example if you want them to be saved on a host computer and not on the **Elisys Duo** Computer), see chapter 7.1.6 on page 7-8.

#### 6.1.4.5 Opening ASCII Result Export Files

Result export files are ordinary (\*.txt) files which can be opened with any standard word processor or spreadsheet software.

They cannot be opened with the **Elisys Duo** software! If you try to open a (\*.txt) result export file with the **Elisys Duo** software, the system will assume that it is a (\*.txt) worklist import file and will automatically display the **ASCII Patient Information Import** dialog as if you had to define import parameters (see chapter 6.1.3 on page 6-5). Just click on the **Cancel** button in this dialog and use the correct software to open the export file.



## 6.2 Communication through an ASTM Link

Communication between the **Elisys Duo** and an external host computer is then accomplished via an RS232 connection and follows the ASTM 1394 (high level) and 1381 (low level) standards for communication.



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*ASTM stands for American Society for Testing and Materials. The ASTM has developed standards on data transfer to/from host computer in the medical field. For more information on ASTM standards, see [www.astm.org](http://www.astm.org).*

---

The **Elisys Duo** host interface consists of:

- ASTM 1381 low-level transfer protocol used to transmit or receive messages
- Interpretation of received data from the intermediate files and entering it into the **Elisys Duo** database

The ASTM 1394 defines how the data to be transmitted is represented as a structured message consisting of several records. These messages are then translated into one or more frames that will actually be transmitted according to ASTM 1381.

### 6.2.1 ASTM Link Set-Up



---

*It is possible to configure the ASTM connection settings if the software is in Demo Mode but not to use the ASTM connection.*

---

To set-up the connection parameters according to ASTM specification for connection to a host computer:

1. Select the **Utilities > Options** menu item.
2. Click on the **ASTM** tab.
3. Click the **Enable ASTM E 1381/1394 link** checkbox. Then all boxes on this tab are enabled. The connection setting of the delimiter and the interface are defined in accordance with the ASTM standard. For other settings, see chapter 7.1.4 on page 7-5
4. Select the correct COM port.
5. Confirm with **OK**.



---

*Please make sure that you do not select the internal COM Port between PC and instrument.*

---

## 6.2.2 Communication Procedure

Communication sessions between the *Elisys Duo* and a host computer can be initiated upon request by the *Elisys Duo* operator or automatically.

### Import of test order requests:

When samples are loaded on the instrument, all tests previously ordered for these samples at host computer level and downloaded to the *Elisys Duo* computer will appear on the column format **Patient Editor** dialog box (see chapter 4.3 on page 4-5). If you have checked the **Query Host For Test Order Requests** item in the **ASTM** dialog, each time you load new samples on the system, the software will automatically interrogate the host computer to know if test order requests are available for these samples.

When a test order request is received from the LIS, a search is first made within the list of LIS assay names/assay protocol filename pairings. If a matching LIS assay name is found, then the software uses the linked assay protocol filename when the test request is effected. If no match is found, the software assumes that the assay name received from the LIS is the exact assay protocol filename.

### Export of test results:

It is possible to export test results manually (via the **Utilities > Export Results** menu item, available when a result report is displayed on the screen) or to configure the *Elisys Duo* software to create and export test results automatically. This is done as described for ASCII files in (see chapter 6.1.4 on page 6-11).

The ASTM format and the data included in the transmission are defined as described in chapter 6.2.1 on page 6-15 and chapter 6.2.5.2 on page 6-20. Additional assay-specific data fields may be included at assay level.

## 6.2.3 Low-Level Protocol

### 6.2.3.1 Physical Layer

(Refer to the ASTM 1381 Standard, section 5)

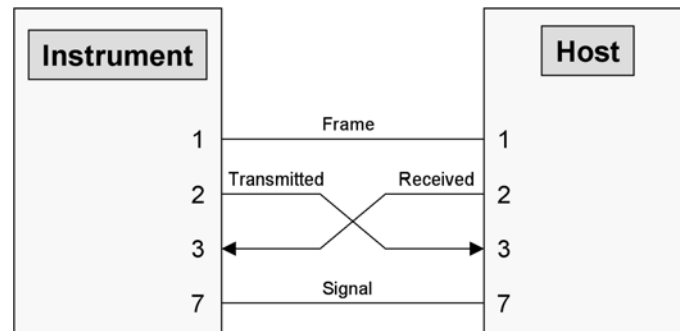


Figure 6-3: RS232 Connection to Host

### 6.2.3.2 Data Link Layer

#### Establishment Phase:

(Refer to the ASTM 1381 Standard, section 6.2)

#### Transfer Phase:

(Refer to the ASTM 1381 Standard, section 6.3)

The checksum is encoded as two characters sent after the <ETB> or <ETX> character. The checksum includes the first character after <STX> (the frame number) up to and including <ETB> or <ETX>. It is computed by adding the binary values of the characters, keeping the least significant eight bits of the result.

During the transfer phase, if the LIS responds to a frame with an <EOT> the **Elisys Duo** does NOT stop transmitting and chooses to ignore the interrupt request.

#### Termination Phase:

(Refer to the ASTM 1381 Standard, section 6.4)

After the **Elisys Duo** transmits or receives the <EOT>, indicating that all messages have been sent, the line is considered to be in the neutral state.

#### Error Recovery:

(Refer to the ASTM 1381 Standard, section 6.5)

The **Elisys Duo** checks every frame it receives to guarantee its validity and sends an <ACK> for a valid frame, or a <NAK> for an invalid frame. Frames are invalidated when:

- Any character errors are detected (i. e. parity error, framing error).
- The frame checksum does not match the checksum computed on the received frame.
- The frame number is not the same as the last accepted frame or one number higher.

When the **Elisys Duo** receives a <NAK> for a frame rejected by a host it resends the frame. If a single frame is sent and rejected six times, the **Elisys Duo** proceeds to the termination phase.

During the establishment phase, the **Elisys Duo** expects to receive a reply within 15 seconds after sending <ENQ>. During the transfer phase, the **Elisys Duo** expects to receive a reply within 15 seconds after transmitting the last character of a frame. If a time-out occurs, the **Elisys Duo** proceeds to the termination phase.

During the transfer phase, the **Elisys Duo** expects to receive a frame or <EOT> within 30 seconds after first entering the transfer phase or replying to a frame. After a time-out, the last incomplete message is discarded and the line is considered to be in the neutral state. The **Elisys Duo** will also time-out if a reply to a frame is not received within 15 seconds.

## 6.2.4 Logical Structure of the Message Level Protocol

The blocked stream of data sent between a host computer and the **Elisys Duo** at a given time is called a message.

Messages consist of a hierarchy of records of various types:

Level	Segment Name	Identifier (Record Type ID)	Comments
0	Message Header Record	'H'	
0	Message Terminator Record	'L'	
1	Patient Information Record	'P'	
1	Request Information Segment	'Q'	
1	Scientific Record	'S'	not allowed for <b>Elisys Duo</b>
2	Test Order Record	'O'	
3	Result Record	'R'	
common	Comment Record	'C'	
1	Manufacturer Information Record	'M'	not allowed for <b>Elisys Duo</b>

Table 6-3: Message Level Protocol

A record is identified by the first field of a record, the RecordTypeID.

Most of the various record types are related to each other in a definite hierarchy:

A lower level record may never appear without the preceding higher level record (i.e. order records must be preceded by a patient record, result records must be preceded by an order record...).

A sequence of records at one level is terminated by the appearance of a record of the same or higher level.

In some other descriptions a record might also be called segment.

## 6.2.5 Incoming and Outgoing Transmission Examples

### 6.2.5.1 Host to *Elisys Duo* (Test Orders)

The host response includes patient demographics, Patient ID, sample ID, and test orders according to the following record hierarchy.

The response to requests for test orders is expected to be received within <Timeout> seconds after the request has been sent. <Timeout> is to be specified in the LISSet-upDialog.

Structure defined by ASTM 1394 (multiple records comprise a single message)		Structure defined by ASTM 1381 (each record is sent as one or more frames)
Message Header Record Patient Information Record 1 Test Order Record 1 : Test Order Record n : Patient Information Record n Test Order Record 1 : Test Order Record n Message Terminator Record	=>	Frame 1 : Frame n

Table 6-4: Structures

In case there are no test orders available the LIS should respond with an empty message containing header and terminator records only. The terminator record should contain an 'I' (no information available) flag in the Termination Code Field.

Example:

```
H\^&||EDVLab|||||1|19941115202738
P|1|PatID01|Anderson^Anna|19741001|F|||MARTINEZ
O|1|SampleID01|^^^AFP^1:10|19980506|||||S|||||||X
P|1|PatID02|Newman^Tony|19741001|F|||MARTINEZ
O|1|SampleID02|^^^AFP|19980506|||||S|||||||X
O|1|SampleID02|^^^TSH|19980506|||||S|||||||X
O|1|SampleID02|^^^T3|19980506|||||S|||||||X
O|1|SampleID02|^^^T4|19980506|||||S|||||||X
P|1|Barcode15|Palmer^John|19741001|F|||MARTINEZ
O|1|Barcode15|^^^AFP^1:10|19980506|||||S|||||||X
P|1|12345|||F|||MARTINEZ
O|1|12345|^^^AFP^1:10|19980506|||||S|||||||X
L|1|N
```

After the *Elisys Duo* receives all test orders from the host, the records are interpreted. Valid test orders are entered into the load list database, while invalid test orders are not.

### 6.2.5.2 *Elisys Duo* to Host (Test Results)

Only the final calculated result (Abs, concentration or interpretation) is transferred per test. For multiple replicate results the mean is transmitted only.

***Elisys Duo*** to Host: (transmit sample information with corresponding tests and results)

Structure defined by ASTM 1394 (multiple records comprise a single message)		Structure defined by ASTM 1381 (each record is sent as one or more frames)
Message Header Record Patient Information Record 1 Test Order Record 1 Result Record 1 Comment 1 : Result Record n Comment 1 : Test Order Record n Result Record 1 Comment 1 : Result Record n Comment 1 : Patient Information Record n Test Order Record 1 Result Record 1 Comment 1 : Result Record n Comment 1 : Test Order Record n Result Record 1 Comment 1 : Result Record n Comment 1 Message Terminator Record	=>	Frame 1 : Frame n

Table 6-5: Structures

Example:

```

H|\^&|||EDVLab|1|19941115202738
P|1|PATID01|ANDERSON^ANNA|19741001|F|||MARTINEZ
O|1|SampleID01|^ ^ ^AFP|19980506|S|F

```

```
R|1|^^^AFP|13.1|IU/ml||H||F|||19980506123145|
L|1|N
```

#### Data Record Usage:

(Refer to the ASTM Standard 1394, particularly sections 6 through 13)

Each record sent by the **Elisys Duo** will contain up to the last field used by the **Elisys Duo**, which may or may not be all fields possible for the record. An 'O' in Required or Sent field indicates optional. The first <MaxLength> characters are significant only. Any more characters transmitted for a specific field are ignored.

### 6.2.5.3 Message Header Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
1	Record Type ID	Character identifying the record as a message header	'H'	1	Y
2	Delimiter Definition	Any received delimiter set is accepted. The delimiters defined in ASTMSetupDialog are sent.		4	Y
3	Message Control ID				N
4	Access Password				N
5	Sender Name / ID			20	N
6	Sender Street Address				N
7	Reserved Field				N
8	Sender Telephone No.				N
9	Characteristics of Sender				N
10	Receiver ID				
11	Comment				N
12	Processing ID				N
13	Version No.		'1'	1	N
14	Date and Time of Message	Format is YYYYMMDD HHMMSS		14	N

Table 6-6: Message Header Record

## Connection to a Host Computer

Communication through an ASTM Link

### 6.2.5.4 Patient Information Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
1	Record Type ID	Character identifying the record as a patient information record	'P'	1	Y
2	Sequence Number				Y
3	Practice Assigned Patient ID				N
4	Laboratory Assigned Patient ID	Becomes our PatientID			Y
5	Patient ID No. 3				N
6^1	Patient Name				O
6^2	Patient First Name				O
7	Mother's Maiden Name				N
8	Birthdate			8	O
9	Patient Sex			1	O
10	Patient Race - Ethnic Origin				N
11	Patient Address				N
12	Reserved Field				N
13	Patient Telephone Number				N
14	Attending Physician ID	Becomes our SenderID			N
15	Special Field 1				N
16	Special Field 2				N
17	Patient Height				N
18	Patient Weight				N
19	Diagnosis				N
20	Active Medications				N
21	Diet				N
22	Practice Field No. 1				N
23	Practice Field No. 2				N
24	Admission and Discharge Dates				N
25	Admission Status				N
26	Location				N



Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
27	Nature of Alternative Diagnostic Code and Classifiers				N
28	Alternative Diagnostic Code and Classification				N
29	Religion				N
30	Marital Status				N
31	Isolation Status				N
32	Language				N
33	Hospital Service				N
34	Hospital Institution				N
35	Dosage Category				N

*Table 6-7: Patient Information Record*

## Connection to a Host Computer

Communication through an ASTM Link

### 6.2.5.5 Test Order Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
1	Record Type ID	Character identifying the record as a test order record	'O'	1	Y
2	Sequence Number				Y
3	Specimen ID				N
4	Patient ID				Y
5^4	Universal Test ID	Test Abbreviation			Y
5^5	Dilution				N
6	Priority				N
7	Requested/ Ordered Date and Time				N
8	Specimen Collection Date and Time	'YYYYMMDDHHMMSS'		14	Y
9	Collection End Time				N
10	Collection Volume				N
11	Collector ID				N
12	Action Code				N
13	Danger Code				N
14	Relevant Clinical Information				N
15	Date/Time Specimen Received				N
16	Specimen Descriptor (Type)				N
17	Ordering Physician				N
18	Physician's Telephone Number				N
19	User Field No. 1				N
20	User Field No. 2				N
21	Laboratory Field No. 1				N
22	Laboratory Field No. 2				N
23	Date/Time Results Reported or Last Modified				N

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
24	Instrument Charge to Computer System				N
25	Instrument Section ID				N
<b>26</b>	<b>Report Types</b>				<b>N</b>
27	Reserved Field				N
28	Location of Ward of Specimen Collection				N
29	Nosocomial Infection Flag				N
30	Specimen Service				N
31	Specimen Institution				N

*Table 6-8: Test Order Record*

### 6.2.5.6 Result Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
1	Record Type ID	Character identifying the record as a result record	R	1	Y
2	Sequence Number				Y
3	Test ID				N
4	Data or Measurement Value			depends on value	Y
5	Units				Y
6	Reference Ranges				Y
7	Result Abnormal Flags				N
8	Nature of Abnormality Testing				N
9	Result Status				N
10	Date of Change in Instrument Normative Values or Units				N
11	Operator Identification				N
12	Date/Time Test Started				N
13	Date/Time Test Completed				N
14	Instrument ID				N

Table 6-9: Result Record

### 6.2.5.7 Comment Record

Comment Records are used either to describe reasons for rejected test orders or to supply additional result information.

One comment record is used for the kit/reagent/control batch number.

Another comment record is used for the relevant flags.

Comment records begins with a C character.

### 6.2.5.8 Request Information Record

Not applicable.

### 6.2.5.9 Message Terminator Record

Field No.	ASTM Field	Description	Valid Contents	Required	Sent
1	Record Type ID	Character identifying the record as the last record in the message	'L'	Y	Y
2	Sequence Number			Y	Y
3	Termination Code			N	N

*Table 6-10: Message Terminator Record*

### 6.2.5.10 Scientific Record

Must not be sent.

### 6.2.5.11 Manufacturer Information Record

Must not be sent.

## Connection to a Host Computer

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Communication through an ASTM Link

# 7 System Configuration

## 7.1 System Options

The **System Set-Up** dialog (see chapter 7.2 on page 7-11) and the **Options** dialog allow you to adapt the **Elisys Duo** system to your specific circumstances and needs. The **Options** dialog lets you specify software options.



*If tabs in the Options dialog aren't shown, this means that you belong to a user group with restricted access rights. For more information on access rights and user groups, see chapter 7.1.1 on page 7-1.*



Click on the **Utilities > Options** item to open the **Options** dialog.

### 7.1.1 Access Control Tab



*Required access rights: Nothing or password (if set)*

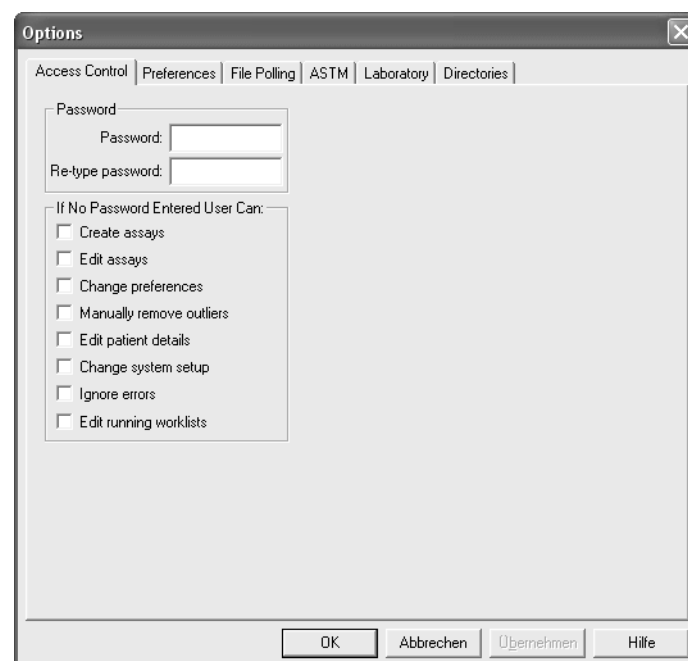


Figure 7-1: Options dialog: Access Control tab

The purpose of this tab is to allow the laboratory supervisor to define the rights of the users without password. For example, it makes it possible to specify that some technicians will only be allowed to use the **Elisys Duo** system to

process pre-defined assays but not to program new assays or change the system settings. It also makes it possible to ensure that only authorized personnel can access patient data or validate results before they are exported to a host computer.

Enter a password to set access rights:

Function	Description
Password	Field for your new password. Any alphanumeric chain of characters can be used as password.
Re-type Password	Field to retry your new password.

Table 7-1: Functions of the Password dialog

This tab includes also a list of access control items (user rights). When an item is checked, this means that users without entered a password can use this function.

Items	When item is checked, user without entered password can...
Create assays	...create new assays.
Change preferences	...access the <b>Preferences</b> tab in the <b>Options</b> dialog and change the settings on this tab (see chapter 7.1.2 on page 7-3).
Change system setup	...open the <b>System Set-Up</b> dialog and change the settings on any of the tabs (see chapter 7.2 on page 7-11).
Edit assays	...edit assays. Note however that even if a group of users is allowed to edit assays, assays themselves can be individually protected by a specific password set by the person or company which created the assay (e.g. validated pre-defined assays are normally password protected).
Edit patient details	...access and edit patient personal information (see chapter 5.2 on page 5-4).
Edit running worklists	...access the <b>Edit &gt; Panel Definition</b> menu item in order to change the settings of an existing worklist (e.g. to add new plates - see chapter 5.6 on page 5-44 on continuous loading).
Ignore errors	...click the <b>Ignore</b> button when error messages are displayed. Ignoring errors is not recommended. However, in some cases, it allows the worklist to continue (even if some wells are flagged) whereas otherwise it would have to be completely aborted. Ignored error messages are traced in the event log.
Manually remove outliers	...remove outliers manually (see chapter 5.5.4.1 on page 5-40).

Table 7-2: List of definable access control items



## 7.1.2 Preferences Tab



*Required access rights: Change preferences*

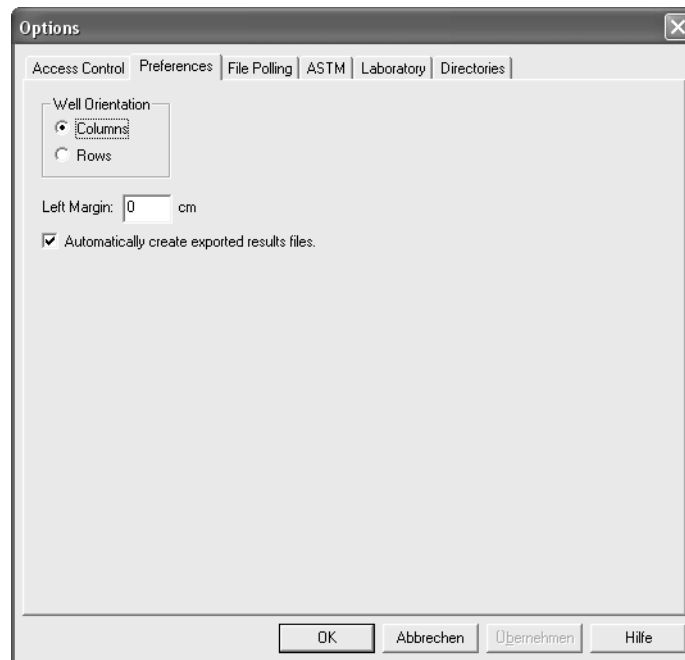


Figure 7-2: Options dialog: Preferences tab

### Well Orientation

Function	Description
Columns	Displays the results column wise.
Rows	Displays the results row wise.

Table 7-3: Functions of the Well Orientation area



*This option is a software option. It does not change the way the pipettor operates. It changes the way the results are displayed. Default is columns.*



*To change the direction in which the pipettor operates, you have to change the fill orientation in the Assay Layout dialog (see "Assay Programming Manual").*

**General**

Function	Description
Automatically create exported results files	Check this option to systematically export the results each time. A result file (*.res) will be generating in the result folder. The result report apply both to ASCII and ASTM exports. Prerequisites for these exports are, however, that the appropriate settings have been defined at assay level (see "Assay Programming Manual") and, for ASTM exports, that the connection has been enabled as described in chapter 7.1.4 on page 7-5.
Left Margin	Defines the left paper margin for printout of the assay protocols and the result report.

*Table 7-4: General functions*

### **7.1.3 File Polling Tab**

See chapter 6.1.3.2 on page 6-8.

## 7.1.4 ASTM Tab



*Required access rights: Nothing*



*The connection setting of the delimiter and the interface are defined in accordance with the ASTM standard.*

### ASTM E 1394

Function	Description
... Delimiter	These fields specify the set of delimiters used for transmissions.
Compact Mode	If this item is checked, each patient result information is sent in a separate package.
ID	Instrument ID is included in the result record.
Query Host For Test Order Requests	If this item is checked, the Query to Host mode is enabled (see below).
Time Out	If no response is received to the query within the time out specified in the field then the software will send no further query requests.

Table 7-5: Functions of the ASTM E 1394 area

### ASTM E 1381

Function	Description
Baud Rate	Specifies the baud rate used for transmissions between the <b>Elisys Duo</b> and the host; any values from 110 to 56,000 can be chosen. Default is 9600.
COM Port	This field specifies the serial port used for host transmissions. Please make sure that you do not select the internal COM Port between PC and instrument.
Create Log File	If this item is checked, a log file (yyyymmdd.txt) of the ASTM communication is created in the C:\Programme\Human\Resources\Event_log directory.
Data Bits	7 or 8, default is 7.
Parity	None, odd, even, mark, space. Default is None.
Stop Bits	1, 1.5 or 2, default is 1.

Table 7-6: Functions of the ASTM E 1381 area

**General**

Function	Description
Assay Links	Click this button to review existing LIS assay names or create new ones..
Enable ASTM E 1381/1394 Link	Select this item if communication with a host computer exists.

*Table 7-7: General functions*

## 7.1.5 Laboratory Tab



*Required access rights: Nothing*

The screenshot shows a window titled 'Options' with a close button (X) in the top right corner. Below the title bar is a tabbed interface with the following tabs: 'Access Control', 'Preferences', 'File Polling', 'ASTM', 'Laboratory', and 'Directories'. The 'Laboratory' tab is selected. Inside the tab, there are four input fields with labels: 'Name:', 'Address:', 'Telephone:', and 'FAX:'. The 'Address' field is a larger text area, while the others are single-line text boxes. At the bottom of the dialog, there are four buttons: 'OK', 'Abbrechen', 'Übernehmen', and 'Hilfe'.

*Figure 7-3: Options dialog: Laboratory tab*

The laboratory details entered here are included in the result reports (see chapter 4.9 on page 4-58).

Function	Description
Address	Address of your laboratory (no specific format is required by the system).
FAX	Fax number of your laboratory (no specific format is required by the system).
Name	Name of your laboratory (no specific format is required by the system).
Telephone	Telephone number of your laboratory (no specific format is required by the system).

*Table 7-8: Functions of the Laboratory tab*

### 7.1.6 Directories Tab



*Required access rights: Nothing*

---

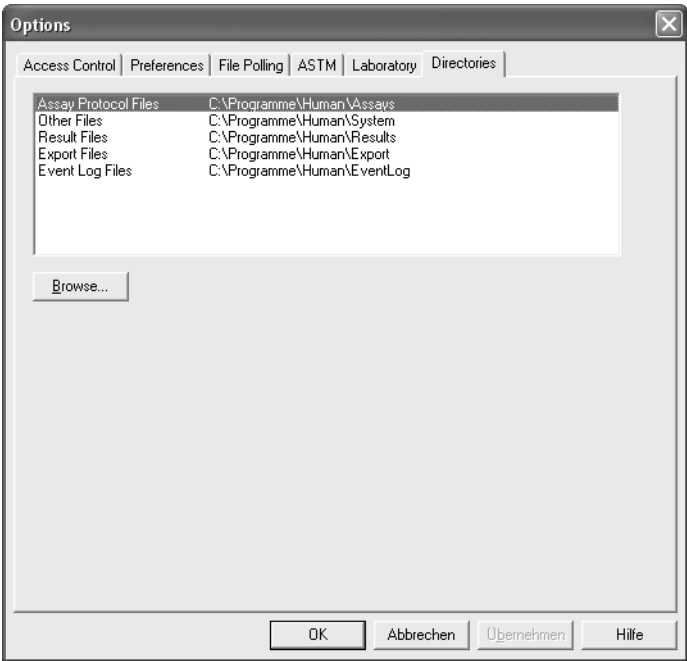


Figure 7-4: Options dialog: Directories tab

Function	Description
Directories	Shows all file types and the path/folder where they are saved.
Browse	Enables to change the path/folder of the file types: <ol style="list-style-type: none"><li>1. Select a file type in the directories list.</li><li>2. Click on the Browse button.</li><li>3. In the Browse dialog, find the directory where you want to save this file type.</li><li>4. In this directory, select any file and click on the Open button (see note below).</li><li>5. Back in the Directories tab, check that the corresponding change has been taken into account.</li><li>6. Confirm with OK.</li><li>7. Repeat this procedure for the other file types if necessary.</li></ol>

Table 7-9: Functions of the Directories tab



*If this new target directory in which you want to save certain file types is empty just copy or create any file into it, so you can select it for that purpose (you can later delete it). If you select only the directory (and no file) and click on the Open button, the change will not be retained.*

---

### 7.1.6.1 File Types and Locations

The **Elisys Duo** software uses a number of different file types. Under default settings these files are saved in the following directories:

Extension	File types	Path/Folder
*.apm	File polling format setting of the import file for host systems.	C:\Pro-gramme\Human\System
*.asy	Assay protocol files.	C:\Pro-gramme\Human\Assays
*.dat	Only one file: Koordina.dat (file containing the system coordinates).	C:\Pro-gramme\Human\System
*.log	Active event log files (documenting daily data communication between PC and <b>Elisys Duo</b> instrument as well as error messages).	C:\Pro-gramme\Human\Event logs
*.mpc	Coordinate files for test plates or dilution plates.	C:\Pro-gramme\Human\System
*.pan	Panel files.	C:\Pro-gramme\Human\Assays
*.rac	Coordinate files for rack types.	C:\Pro-gramme\Human\System
*.rea	Reagent layout files.	C:\Pro-gramme\Human\System
*.res	Result files.	C:\Pro-gramme\Human\Results
*.spe	Spectrum files (contain data of a spectrum acquisition).	C:\Pro-gramme\Human\System
*.tst	Selftest report files with information about the selftests that were performed.	C:\Pro-gramme\Human\System
*.txt	Export files in ASCII format	C:\Pro-gramme\Human\Export
*.txt	ASCII patient data import files can be downloaded from a host computer to the <b>Elisys Duo</b> software (patient with associated assays).	C:\Pro-gramme\Human\Import or selected directory on host computer
*.txt	Duplicate log file in (*.txt) format.	C:\Pro-gramme\Human\Event logs
*.ver	Photometer verification report files.	C:\Pro-gramme\Human\System
*.wor	Worklist files.	C:\Pro-gramme\Human\Assays

Table 7-10: File types and locations



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*The system uses also some other file types (\*.rec, \*.db, \*.mdb, \*.lsv, \*.con) but these are hidden for the user.*

---

If, when installing the software, you have chosen to install it in a different directory than the default directory, you will have to edit manually the default directory for each file type as described below. This can be a source of errors. Therefore, unless you have a specific reason to do otherwise, it is recommended that you install the **Elisys Duo** software in the default directory.



## 7.2 System Set-up



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*Required access rights: Change system setup*

---



The **System Set-Up** dialog and the **Options** dialog (see chapter 7.1 on page 7-1) allow you to adapt the **Elisys Duo** system to your specific circumstances and needs. The **System Set-Up** dialog allows you to adapt the parameters of each instrument module (incubators, pipetting system, wash unit, etc.).

Click on the **Utilities > System Setup** item to open the **System Set-Up** dialog.

7.2.1 System Tab

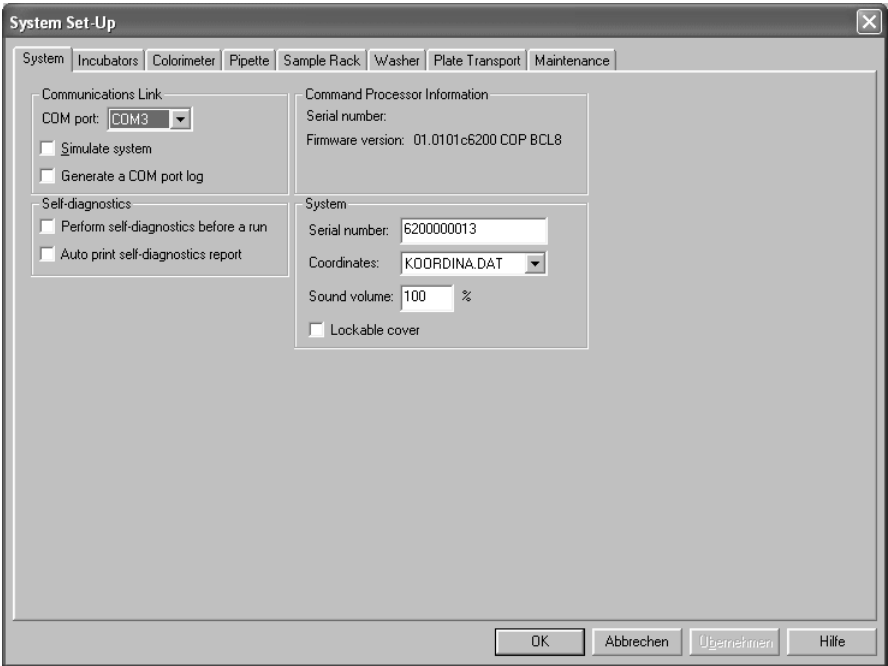


Figure 7-5: System Set-Up dialog: System tab

Communications Links

Defines the PC's communication link to **Elisys Duo** instrument.

Function	Description
COM port	Select the COM port for the computer-to-instrument link. Default is COM port 1 (see chapter 6 on page 6-1).
Simulate system	This item is automatically checked when you check the <b>Demo mode</b> item in the <b>Log-On</b> dialog (see chapter 4.2 on page 4-3).
Generate a COM port log	Select this item to document communication via the selected COM port in a log file.

Table 7-11: Functions of the Communications Links area

Self-diagnostic

Enables an additional check of the **Elisys Duo** instrument.

Function	Description
Perform self-diagnostics before a run	Select this item to perform automatically a self test before run a worklist (see chapter 5.1 on page 5-1).
Auto print self-diagnostics report	Select this item to print automatically the self test result report.

Table 7-12: Functions of the Self-diagnostics area

## System

Function	Description
Coordinates	Shows the used coordinates file.
Lockable cover	Activates the cover lock. This means that the cover is locked during a run. See warning below!
Serial number	Serial number of the <b>Elisys Duo</b> instrument. This number will be needed if you call your representative for support or service.  The serial number is also printed on the type label (see chapter 1.4.5 on page 1-13).
Sound volume	Volume of the audible signal.

Table 7-13: Functions of the System Serial Number area



**Never deactivate the cover lock for normal use. There is a high risk about injuries.**

## Command Processor Information

Information on the **Elisys Duo** central operation processor (COP).

Function	Description
Serial number	Shows the COP serial number
Firmware version	Shows the COP firmware version.

Table 7-14: Functions of the Command Processor Information area

7.2.2 Incubators Tab

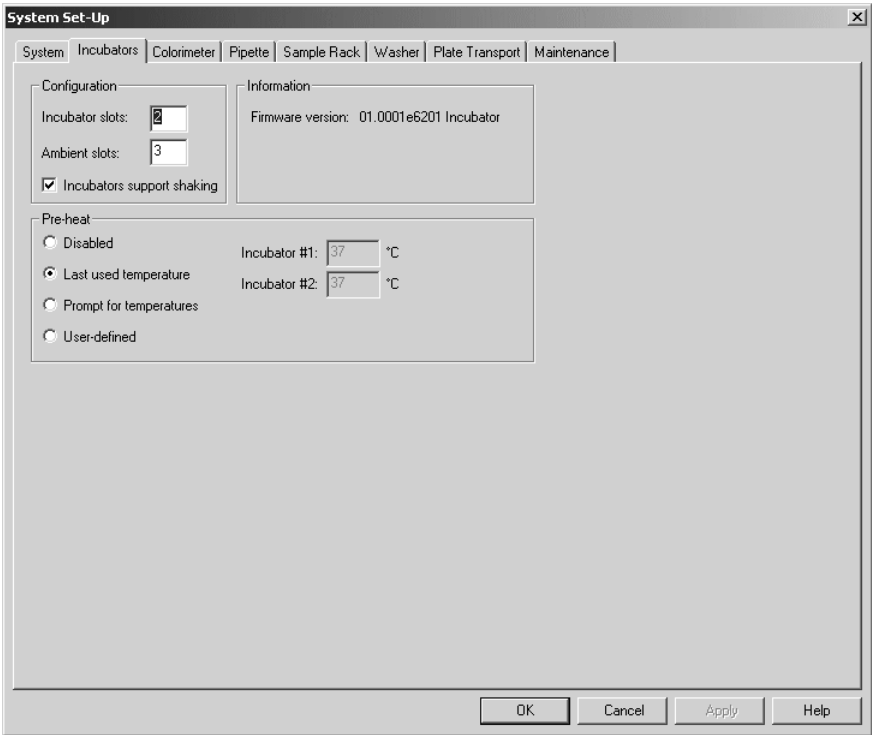


Figure 7-6: System Set-Up dialog: Incubators tab

Configuration

Function	Description
Incubator slots	Specify how many heat able incubators are to be used.
Ambient slots	Specify how many room-temperature incubators are to be used.
Incubators support shaking	Enable the shaking function of the heat able incubators.

Table 7-15: Functions of the Configuration area

Pre-heat

Setting for the incubators preheat function on power-up. The incubators take some time to reach high temperatures. The system will not start a run if the temperatures required for the assays to be processed are not reached. If you intend to process assays with high incubation temperatures, it is a good idea to select a pre-heating on power-up option.

Function	Description
Disabled	Incubators are not preheated on power-up.
Last used temperature	Incubators are preheated to the last used temperature on power-up (default setting).
Prompt for temperatures	Incubators are preheated to the temperature selected in the window coming up on power-up.
User-defined	Incubators are preheated to the temperature defined in the fields for Incubator #1 and Incubator #2 on power-up (values between 21 and 55 can be entered).
Incubator #1, Incubator #2	(see User-defined)

Table 7-16: Functions of the Pre-heat area

**Information**

Incubators information.

Function	Description
Firmware version	Shows the firmware version number for the incubators.

Table 7-17: Function of the Information area

### 7.2.3 Colorimeter Tab (Photometer)

In the software and in this manual, the words "photometer" and "colorimeter" are synonymous.

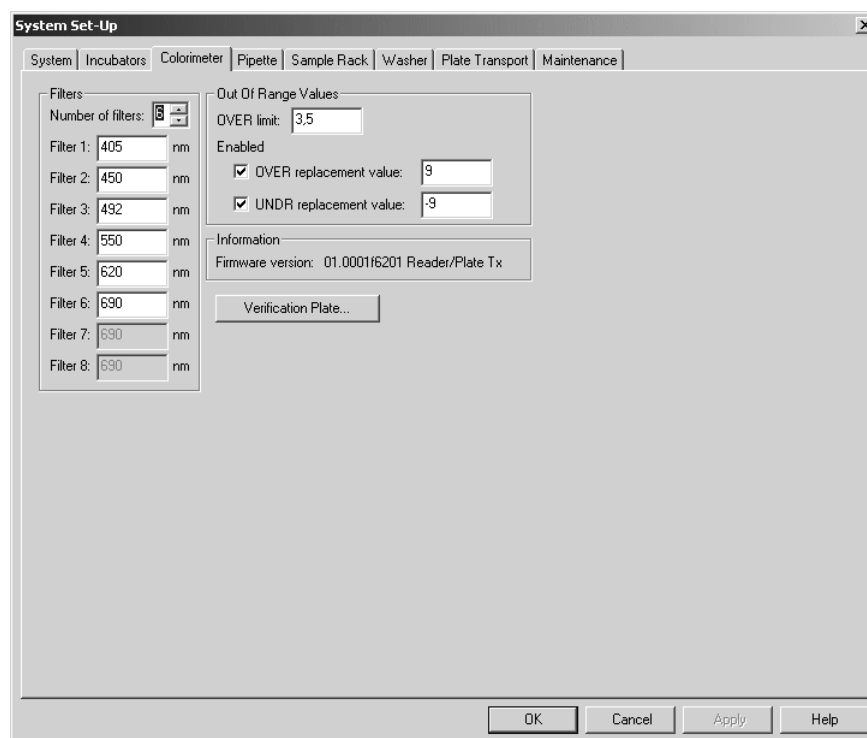


Figure 7-7: System Set-Up dialog: Colorimeter tab

#### Filters

By default, the photometer on the **Elisys Duo** instrument is equipped with two filters. Two more filters can be added to suit the user-specific needs. To add filters, contact your service engineer.



*The system is not able to check automatically in which position each filter is installed. When the system is installed, the appropriate data is entered in the software by your service engineer using the Colorimeter tab below. If you ever add or change filters, always make sure the parameters specified in the software (number of filters, order, wavelengths) strictly correspond to the filters that are on the instrument.*

Function	Description
Number of filters	Number of filters used in the instrument (default is 6).
Filter 1 - Filter 8	The number of boxes that are enabled depends on the number that has been specified above. Shows the wavelength of each filter in nm. The numbering of the filter in the instrument must match the numbering on this tab! Defaults: <ul style="list-style-type: none"> <li>• Filter 1: 450 nm</li> <li>• Filter 2: 620 nm</li> </ul>

Table 7-18: Functions of the Filters area

## Out Of Range Values

Function	Description
OVER limit	Enter the upper limit value (OD) for the photometer (e.g. 2.5). The maximum value that can be set is 3.5. The lower limit value is equal to the negative value of the upper limit value. The photometer is linear up to 2.000.
OVER replacement value and UNDR replacement value	When the value read by the photometer is OVER the upper limit (or UNDER the lower limit), you can choose to replace, in the results, the actual value by another character string, e.g. a wildcard (*), a digit or a comment. In this case, check the item and enter the replacement string in the respective field (default is a wildcard sign).

Table 7-19: Functions of the Out Of Range Values area

## Information

Photometer information

Function	Description
Firmware version	Shows the firmware version number.

Table 7-20: Functions of the Information area

## General

Function	Description
Verification Plate	Enables to enter the reference values of the reader verification plate. You don't need this function, if you use the verification plate data disk. See 'Reader Verification Plate Manual' for photometer verification.

Table 7-21: General functions

## 7.2.4 Pipette Tab



The Pipette tab is used to define the Pipetting parameters at system level, i.e. to define how the pipettor works. Do not confuse it with the Pipette dialog or the Dispense dialog (see "Assay Programming Manual") which are used to define, at assay level, which aspirate/dispense steps the pipettor should execute.

**System Set-Up**

System Incubators Colorimeter **Pipette** Sample Rack Washer Plate Transport Maintenance

**Options**  
 Syringe volume: 1000 ul  
☒ Disposable tips  
☐ Enable clot detection  
☒ Enable liquid level detection

**Dilution Plates**  
 Coordinates: nunc2ml.mpc  
 Maximum Volume: 2000 ul  
 Minimum Volume: 300 ul

**Dilution Tubes**  
 Max. Volume: 10000 ul  
 Min. Volume: 100 ul  
 Colour: [Dropdown]

**Information**  
 Firmware version: 01.0103a6205 PIP Pipettor

**Aspirate Profile**  
 Profile number: 0  
 Description: Multi Disp Asp  
 Start velocity: 500 Hz  
 Top velocity: 1000 Hz  
 Acceleration: 2 x2.5 kHz/s  
 Airgap: 0 ul  
 Dive out velocity: 10 %  
 Dive out: 400 Steps  
 Submerge steps: 0 Steps  
 LLD Speed: 100 %  
 Transportation airgap: 10 ul  
 Aspirate delay: 5 x0.1 s

**Dispense Profile**  
 Profile number: 0  
 Description: Multi Disp  
 Start velocity: 800 Hz  
 Top velocity: 5000 Hz  
 Acceleration: 20 x2.5 kHz/s  
 Cutoff velocity: 2000 Hz  
 Dive out velocity: 10 %  
 Dive out: 400 Steps  
 Resoak: 10 ul  
 Dispense delay: 2 x0.1 s  
 Submerge steps: 0 Steps

**Active washing**  
 Dive out velocity: 5 %  
 Dive out: 5 Steps

**LLD Parameters**  
 Reagents: 0 Verifies 0 Retries Bubble Kill  
 Samples: 0 Verifies 0 Retries Bubble Kill

**Sample Tubes**  
 Colour: [Dropdown]

OK Abbrechen Übernehmen Hilfe

Figure 7-8: System Set-Up dialog: Pipette tab



## Options

Function	Description
Syringe volume	Shows the syringe volume of the pipettor pump in microliters (1000 µl).
Disposable tips	This item is always checked (it ensures that a warning message is displayed if a problem occurs when the pipettor picks up or ejects a tip).
Enable clot detection	This item is always checked. It ensures that a warning message is displayed if a clot is detected.
Enable liquid level detection	This item is always checked. The liquid level detection process enables the system to monitor the height at the surface of the respective liquid. It then calculates how the pipettor should move during aspiration/dispense in relation to the surface of the liquid and the volume to be aspirated/dispensed.
Enable pressure monitoring	Check this item to enable the aspirate pressure monitoring system (APM). If APM is enabled, the system compares the measured aspiration pressure data with thresholds in order to detect pressure errors immediately after the aspiration.

Table 7-22: Functions of the Options area

## Dilution Plates

See also chapter 4.7.5 on page 4-41

Function	Description
Coordinates	The parameters offered here are based on a (*.mpc) file. Here you select the dilution plates used. The respective file must be in the <b>Elisys Duo</b> program directory (C:\Programme\Human\System).
Maximum Volume	Enter the maximum volume of a cavity of the dilution plate.
Minimum Volume	Enter the minimum detectable volume of a cavity of the dilution plate.

Table 7-23: Functions of the Dilution Plates area

## Dilution Tubes

Information about the dilution tubes. Dilution tubes may be used for sample archiving and pre-dilution steps (for assays for which such a step is necessary).

Function	Description
Max. Volume	Enter the maximum volume of a dilution tube.
Min. Volume	Enter the minimum detectable volume of a dilution tube.
Colour	Select the colour in which dilution tubes are displayed in the Load dialog.

*Table 7-24: Functions of the Dilution Tubes area*

**Information**

Pipettor information.

Function	Description
Firmware version	Shows the current firmware version of the pipetting system.
Bridge version	Shows the current firmware version of the X-motor controller main system.
X-axis version	Shows the current firmware version of the X-motor controller.
Z-axis version	Shows the current firmware version of the Y-/Z-motor controller.

*Table 7-25: Functions of the Information area*

**Aspirate Profile**

See also chapter 7.2.4.1 on page 7-23 below on pipetting profiles.

Function	Description
Profile number	Select the profile which you want to view or edit.
Description	Name of the aspirate profile.
Start velocity	Velocity at the start of aspiration (in Hz).
Top velocity	Maximum aspirate velocity (in Hz).
Acceleration	Enter the acceleration of the aspirate velocity in kHz/s.
Airgap	This airgap is aspirated before a reagent and blown out after the reagent to ensure the full dispense of the reagent.
Dive out velocity	Velocity in percent of the maximum velocity used to move the tip out of the liquid.
Dive out	Distance the tip has to travel up when being moved out of the liquid in steps of the stepper motor.
Submerge steps	Number of steps the tip is to submerge into the liquid following liquid detection.
LLD Speed	Velocity of liquid detection in percent of the maximum velocity.
Transportation airgap	This airgap is aspirated after a reagent.
Aspirate delay	Delay time after aspiration to allow the liquid to settle.

Table 7-26: Functions of the Aspirate Profile area

## Dispense Profile

See also chapter 7.2.4.1 on page 7-23 below on pipetting profiles.

Function	Description
Profile number	Select the profile which you want to view or edit.
Description	Name of the dispense profile.
Start velocity	Velocity at the start of dispensing (in Hz).
Top velocity	Maximum dispense velocity (in Hz).
Acceleration	Enter the acceleration of the dispense velocity (in kHz/s).
Cutoff velocity	Cutoff velocity in Hz (stop velocity).
Dive out velocity	Velocity in Hz with which the tip is moved out of the liquid.
Dive out	Distance the tip to travel when being moved out of the liquid (in steps of the stepper motor).
Resoak	Define how much liquid in µl is resoaked again after dispensing.
Dispense delay	Delay time before dispensing (the pipettor moves from the reagent bottle to the test plate and waits) to allow the liquid to settle.
Submerge steps	Number of steps the tip is to submerge into the liquid following liquid detection.

*Table 7-27: Functions of the Dispense Profile area*

**Active washing**

Pipette parameters for washing:

Function	Description
Dive out velocity	Velocity in Hz with which the tip is moved up out of the liquid. This should be set slower than the normal velocity.
Dive out	Distance the tip has to travel when being pulled out of the liquid (in steps of the stepper motor).

*Table 7-28: Functions of the Active washing area*

**Sample Tubes**

See also chapter 4.7.2 on page 4-34.

Function	Description
Colour	Select the color in which sample tubes are displayed in the Load dialog.

*Table 7-29: Functions of the Sample Tubes area*

**LLD Parameters**

Liquid Level Detection parameters:

Function	Description
Verifies	Do not change the default settings.
Retries	Do not change the default settings.
Bubble Kill	Do not change the default settings.

Table 7-30: Functions of the LLD Parameters area

### 7.2.4.1 Pipetting Profiles

The purpose of pipetting profiles is to optimize the pipetting process (e.g. increase accuracy and precision, avoid dripping, air bubbles, splashing, hanging drops, etc.) by adjusting the pipetting parameters to the type of liquid (samples, controls, reagents) which is aspirated/dispensed and to other specific circumstances (e.g. multi-shots, low volumes, large volumes, etc.).

#### Defining Pipetting Profiles

Defining pipetting profiles is done at system level, using the **Aspirate Profile** and the **Dispense Profile** fields in the **Pipette** tab (see above). However, defining pipetting profiles is a fairly complex process which requires a good knowledge of how the pipettor operates and adequate testing.

This is why the software includes some pre-defined profiles.

Profile Number:	Description:
0 to 4 (included)	Pre-defined profiles. These profiles are protected (read-only). They cannot be edited but the profile parameters can be viewed in the <b>Pipette</b> tab.
5 to 9 (included)	User-definable profiles. To define a new profile, select one of these profiles (e.g. Aspirate 6), rename it and enter the desired
10 to 19 (included)	Pre-defined profiles. These pre-defined profiles are included in the software but they are "hidden". This means that you can use them (see below) but you cannot view them in the <b>Pipette</b> tab (this is why the Profile number field only scrolls up to 9).

Table 7-31: Profile description

This adds up to a total of 20 possible aspirate profiles and 20 possible dispense profiles.

#### Using a Pipetting Profile

If you are using pre-defined assays, the profiles to be used for each aspirate or dispense operation are already specified in the assay.

If you are creating your own assays, you have to specify the profiles you want to use:

- when you define your **Pipetting steps** (see "Assay Programming Manual"),
- and when you enter your reagent data in the reagent database (see "Assay Programming Manual").

## System Configuration

---

### System Set-up



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*Because of wrong profile settings (problem spillages) it is necessary to validate assays!*

---

### Troubleshooting

Defining profiles or even selecting the right profile to use can be difficult in some cases. If in doubt, contact your application engineer.

## 7.2.5 Sample Rack Tab

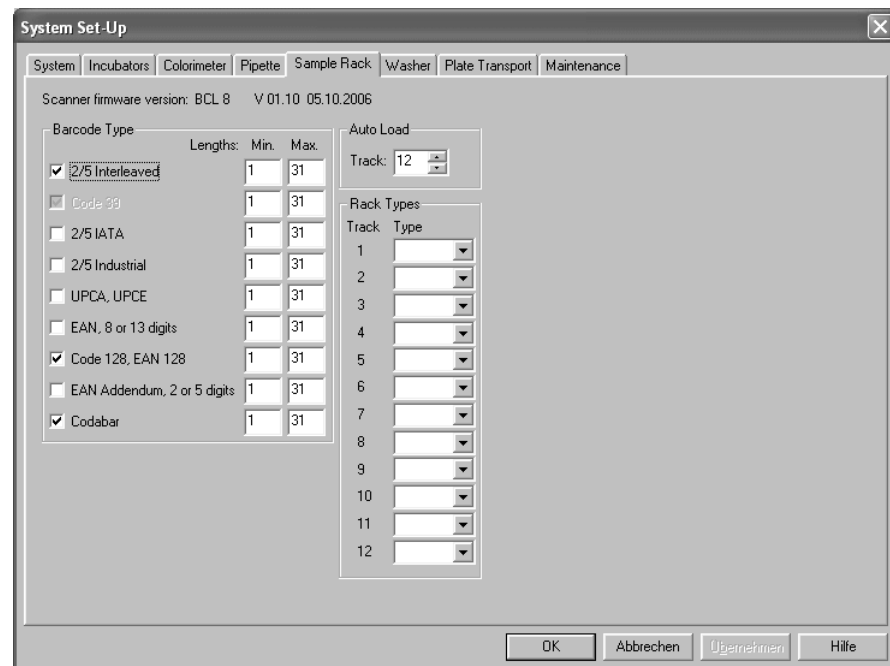


Figure 7-9: System Set-Up dialog: Sample Rack tab

### Scanner firmware ver- sion

Function	Description
Scanner firmware version	Reference of the scanner firmware installed on the system.

Table 7-32: Functions of the Barcode Type area

## Barcode Type

Function	Description
Barcode Type	<p>List of all bar code types that can be read by the integrated bar code scanner. If a checkbox is selected, the scanner is able to read the respective bar code type. It is possible to select several checkboxes but the more checkboxes are selected, the slower and less accurate the reading will be.</p> <p>Some bar codes types are always selected and cannot be unchecked (bar code types used on <b>Elisys Duo</b> racks and reagents).</p> <p>The following bar code types can be used for samples and reagents to be processed on the <b>Elisys Duo</b> system:</p> <ul style="list-style-type: none"> <li>• 2/5 Interleaved,</li> <li>• Code 39,</li> <li>• 2/5 IATA,</li> <li>• 2/5 Industrial,</li> <li>• UPCA, UPCE,</li> <li>• EAN 8 or 13 digits,</li> <li>• Code 128, EAN 128,</li> <li>• Pharmacode,</li> <li>• EAN Addendum, 2or 5 digits,</li> <li>• Codabar.</li> </ul> <p>Typically, when the system is installed, your service engineer configures the bar code scanner to accept the bar code types you generally use on the samples you process.</p> <p>If you later need to change the preconfigured bar code settings, see chapter 7.2.5.1 on page 7-27.</p>
Lengths Min. Max.	<p>Minimum and maximum character length of each bar code type.</p> <p><b>Note:</b> Generally, if you do not know these values, you can leave the default values. However, if you also use the <b>Prefix</b> and <b>Suffix</b> options to exclude some digits (see below), you should enter in the <b>Min.</b> and <b>Max.</b> fields exactly the number of significant digits (including the prefix and suffix) in the respective bar code type. For example, if you use a bar code format with 14 digits altogether and exclude the date suffix (6 digits), enter "14" in both the <b>Min.</b> and <b>Max.</b> fields.</p> <p><b>Note:</b> Wrong settings could lead to false bar code values.</p> <p>Example:</p> <ul style="list-style-type: none"> <li>• <b>Max.</b> = 6</li> <li>• Bar code 1: 2007P45</li> <li>• Bar code 2: 2007P48</li> <li>• Result: 2007P4 for both bar codes!</li> </ul>

Table 7-33: Functions of the Barcode Type area



**If you change the bar code settings (e. g. length, checksum) it is necessary to validate this settings with your bar codes.**





*For better reading accuracy, select only those bar code types which you actually use. Never select all bar code types.*



*To edit the bar code settings just before a run (e. g. to select a bar code type which you specifically need for this run) you can access this dialog by clicking the **Scanner Setup** button in the **Load** dialog.*

## Auto Load

Function	Description
Track	Enter the first line to be loaded.

Table 7-34: Functions of the Auto Load area

## Rack Types

If a rack is identified through bar codes, the rack type is automatically displayed. If identification via bar codes was not possible (damaged or dirty bar codes), you have to select the rack type manually.

With three-track racks the same rack type must occupy the respective tracks.

Function	Description
Track	Lane of the sample and reagent unit.
Type	Rack type.

Table 7-35: Functions of the Rack Types area

### 7.2.5.1 Using several Bar Code Types

You will frequently have to select several bar code types, e.g. when a laboratory uses one set of bar codes for racks and sample tubes differ from one customer to the other.

In this case, click the corresponding checkboxes. The scanner will work faster and more precisely if you choose fewer bar code types. Choose only those you will use. Never check all the bar code types.

#### **If you don't know the type of barcode used**

In most cases, the types of bar codes used are specified by the suppliers of the various accessories or products. However, it can happen that the user does not know the type of bar code used. For example, if a laboratory receives bar coded samples or reagent containers but is not sure of the type of bar code used.

What you can do to identify the bar code type:

1. Fit the bar coded sample(s) in a rack.
2. Select the **Utilities > System Setup** menu item and click on the **Sample Rack** tab.
3. Select three deselected barcode types (notice them).
4. Click on the **OK** button.
5. Insert the rack in its lane.
6. When the **Patient Editor** dialog opens (see chapter 4.3.1 on page 4-5), check the first column.
7. If the system has not been able to read the bar codes, the first column is blank. In this case, click on the **Close** button in the

- Patient Editor dialog, remove the rack, open the Sample Rack tab again, and repeat the procedure for three other bar codes (deselect the previous bar codes).
8. If the system has been able to read the bar codes, the patient IDs are already displayed in this first column. In this case, click on the Close button in the Patient Editor dialog, remove the rack, open the Sample Rack tab again, and select each of these three barcode types one at a time and, for each type, pull out the rack and then re-insert it until you determine which of the three bar code types is correct.

#### 7.2.5.2 Rack Bar Codes

All **Elisys Duo** sample and reagent racks are bar coded. The bar code labels are located on the right-hand side of each rack. They serve to identify both the rack type and individual positions on each rack.

The system is preconfigured to be able to read the rack bar codes. It is recommended not to use racks with missing or damaged bar codes. Replaced bar code labels for **Elisys Duo** racks can be ordered. However, if you need to use non-bar coded racks (or racks with damaged labels), follow the instructions in chapter 5.5.2.3 on page 5-37 and allocate the on-board samples or reagents manually.



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*Rack bar codes are used by the system to identify different rack types but not individual racks. For example, the system can differentiate a reagent rack from a sample rack or a "T" sample rack from a "Z" archiving rack but it cannot differentiate one "T" sample rack from another "T" sample rack.*

---

#### 7.2.5.3 Reagent Bar Codes

Most reagents included in kits are bar coded. In some cases, bar code labels are provided in the kits and need to be attached to the respective vials before use. In some cases, bar code labels can be ordered separately.

The bar code settings of the **Elisys Duo** system are preconfigured so that the system can read all bar code types used on reagent bottles.

## 7.2.6 Washer Tab

The parameters of the wash unit are entered by your service engineer when the **Elisys Duo** system is first installed.

**System Set-Up**

System | Incubators | Colorimeter | Pipette | Sample Rack | **Washer** | Plate Transport | Maintenance

**Reagent Bottles**

Number of reagent bottles: 8

1 litre bottle dead volume: 175 ml

2 litre bottle dead volume: 350 ml

	Capacity	Default Reagent
Red:	2 litre	
Blue:	2 litre	
Yellow:	2 litre	

Check reagent: Once per wash cycle

**Purging**

Volume (ul/tip): 4000

**Cleaning**

Volume (ul/tip): 4000

Fluid: Clean Fluid

Reagents...

☒ Clean after every wash step

**Default Heights**

Top Wash Height: 40 Show

Bottom Wash Height: 100 Show

Aspirate Height: 134 Show

**Information**

Firmware version: 01.0002g6201 Washer/Pipettor

Calibrate

OK Cancel Apply Help

Figure 7-10: System Set-Up dialog: Washer tab

On defining wash steps in an assay, see "Assay Programming Manual".

**Reagent Bottles** Parameters for the wash buffer and clean fluid containers.

Function	Description
Number of reagent bottles	Number of wash buffer/clean fluid containers used (default is 3).
1 litre bottle dead volume	Dead volume of each wash buffer/clean fluid container in ml.
2 litre bottle dead volume	Dead volume of each wash buffer/clean fluid container in ml.
Capacity	Use these items if you want to use a 1-liter bottle or a 2-liter bottle for the Red, Blue, or Yellow channel. The change will be reflected in the Load dialog display of the wash buffer/clean fluid bottles (see chapter 4.7.1 on page 4-30). In any case, always make sure what is specified in the software corresponds to the actual wash buffer/clean fluid bottles loaded on the instrument.
Default Reagent	With these drop-down lists, you can change a default reagent so that a given wash buffer should always be assigned to a specific bottle for the Red, Blue, or Yellow channel. The change will be reflected in the Load dialog display of the wash buffer/clean fluid bottles (see chapter 4.7.1 on page 4-30).
Check reagent	The wash buffer volume sensor (float switch) is checked at the beginning of each wash cycle. <b>Note:</b> Always activate this function. Deactivation may lead to incorrect washing in case remaining buffer is not sufficient for complete cycle and should not be used.

Table 7-36: Functions of the Reagent Bottles area

**Default Heights** Set the height of the dispensing needle during washing.

Function	Description
Top Wash Height	Aspiration needle on the level of the upper edge of the plate.
Bottom Wash Height	Aspiration needle on a level slightly above the well bottom. On this level, the dispense tip is also in the liquid for intense washing of the wells (simultaneous aspiration during dispensing).
Aspirate Height	Aspiration needle on the same level as the well bottom. Set the height such that the aspiration needles. Notches in the aspiration needles prevent that the washer heads get stuck.
Show	You can check the exact height setting as follows: Enter a height (0 means: highest position of dispensing needle.) and click the <b>Show</b> button. The dispensing needle is then moved to the defined height. If the setting is not yet adequate, correct the height and click the <b>Show</b> button again. Should be done only by your service engineer.

Table 7-37: Functions of the Default Heights area

**Information**

Washer information.

Function	Description
Firmware version	Shows the current firmware version of the washer.

Table 7-38: Functions of the Information area

**Purging**

Purge parameters (= cleaning before the first wash step of the worklist).

Function	Description
Volume	Purge volume in $\mu\text{l}$ per tip.

Table 7-39: Functions of the Purging area

**Cleaning**

Cleaning parameters.

Function	Description
Volume	Cleaning volume (µl per tip).
Fluid	Select a reagent/buffer for cleaning.
Reagents	If the desired buffer is not available in the drop-down list, you may define or load another wash buffer by clicking the <b>Reagents</b> button (this opens the Buffer section of the <b>Reagent Database</b> and lets you select or create the desired buffer, see "Assay Programming Manual").
Clean after every wash step	Select this item if you want to clean after each wash step.

*Table 7-40: Functions of the Cleaning area*

**General**

Function	Description
Calibrate	Click this button to perform an internal calibration of the 3 dosing units of the wash system.

*Table 7-41: General functions*

## 7.2.7 Plate Transport Tab

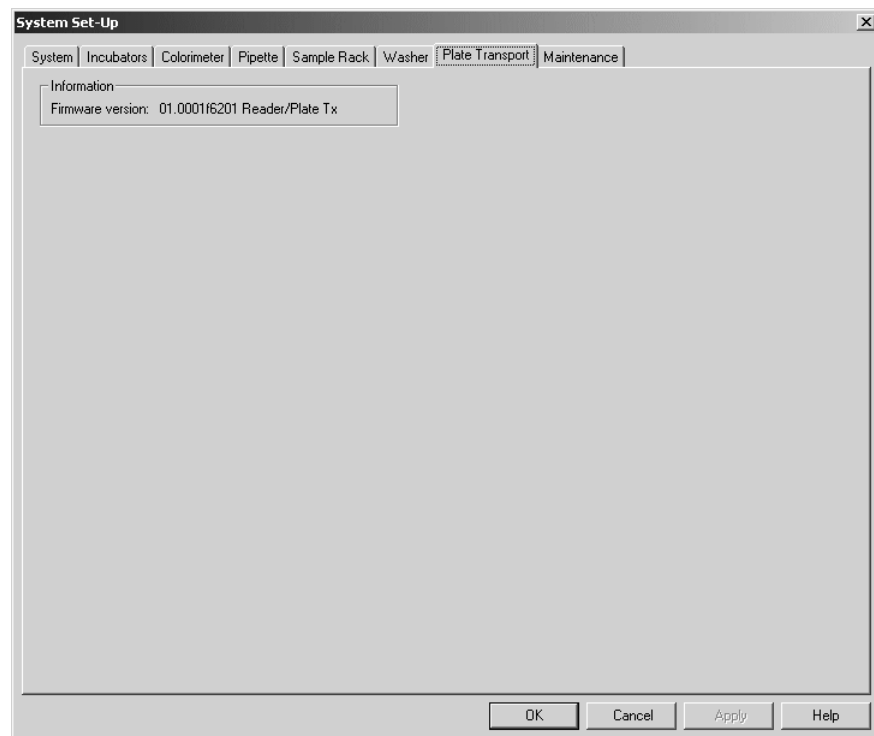


Figure 7-11: System Set-Up dialog: Plate Transport tab

### Information

Plate transport information.

Function	Description
Firmware version	Shows the current firmware version of the plate transport.

Table 7-42: Functions of the Information area

## 7.2.8 Maintenance Tab

As part of its normal operating routine, the **Elisys Duo** system performs a number of maintenance jobs automatically. For example:

- During each selftest (see chapter 5.1 on page 5-1), the system checks the status of all instrument modules.
- During each run, the pipettor is primed with system liquid.
- Following each wash step, the washer is purged with clean fluid (deionised water).

These maintenance jobs are controlled automatically without any user intervention.

But the **Elisys Duo** system also includes a feature allowing users to predefine some maintenance tasks and maintenance reminders.

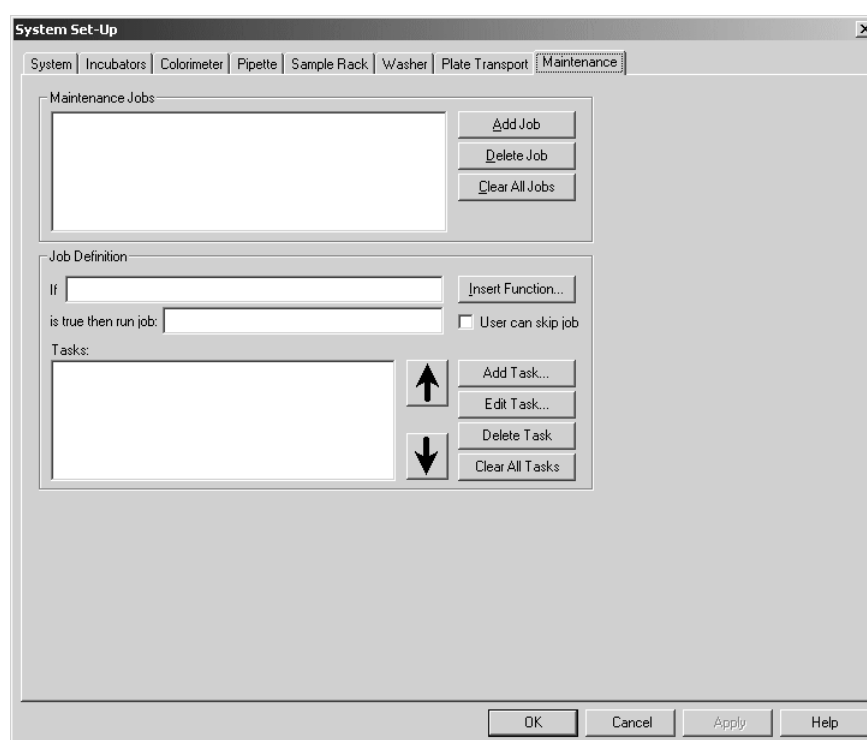


Figure 7-12: System Set-Up dialog: Maintenance tab

### Maintenance Jobs

Function	Description
Maintenance Jobs	Shows the name of all created maintenance jobs.
Add Job	Adds a new maintenance job to the maintenance job list.
Delete Job	Deletes a selected maintenance job.
Clear All Jobs	Deletes <b>all</b> maintenance jobs.

Table 7-43: Functions of the Maintenance Jobs area



## Job Definition

Function	Description
If	Specifies the condition to be fulfilled to perform a certain maintenance job.
is true then run job	Name of the maintenance job to be performed if the specified condition is fulfilled.
Insert Function	Shows the Insert Function dialog to select a function.
User can skip job	This option allows the user to skip an incidental maintenance job. The maintenance job can then be performed later.
Tasks	Indicates all actions to be performed if the maintenance job is started.
Arrows	By means of the arrows, the position of a selected action can be changed. The actions are performed according to their sequence.
Add Task	<p>Inserts a new task.</p> <p>Possible tasks:</p> <ul style="list-style-type: none"> <li>• <b>Display message:</b> With the action <b>Display message</b>, a message can be displayed on the screen during the performance of a maintenance job. The user must acknowledge this message.</li> <li>• <b>Prime pipettor:</b> This action allows the cleaning of the pipettor. With an input dialog, the volume to be aspired can be specified.</li> <li>• <b>Purge washer:</b> With this action, the washer can be cleaned. With an input dialog, the bottle to be used and the volume can be entered.</li> <li>• <b>Verify colorimeter:</b> Allows the verification of the reader. With an input dialog, the filters to be checked can be selected.</li> </ul>
Edit Task	Allows the editing of a selected action.
Delete Task	Deletes a selected task.
Clear All Tasks	Deletes <b>all</b> tasks.

Table 7-44: Functions of the Job Definition area

### 7.2.8.1 Functions for Maintenance Jobs

Function	Description
IF	IF(condition;then;else) If the condition is true the "then" expression is evaluated, otherwise the "else" expression.
AND	AND(condition;...) Returns true if all of the conditions evaluate to true, otherwise returns false.
OR	OR(condition;...) Returns true if any of the conditions evaluate to true, otherwise returns false.
Days	The number of days since this reminder was last displayed.
Plates	The number of plates processed since this reminder was last displayed.
Samples	The number of samples processed since this reminder was last displayed.
Tips	The number of tips used since this reminder was last displayed.
Worklists	The number of worklists processed since this reminder was last displayed.
abs	ABS(value) Returns the absolute value of the value argument.
log	LOG(value) Returns the base 10 logarithm of value.
alog	ALOG(value) Returns the base 10 anti-logarithm of value.
ln	LN(value) Returns the natural logarithm of value.
exp	EXP(value) Returns the natural anti-logarithm of value.
Int	INT(value) Returns the integer part of value.
ROUND	ROUND(value) Returns the nearest integer value.

Table 7-45: Functions of the Insert Function dialog

### 7.2.8.2 Definition of Maintenance Jobs

#### Example 1

#### Defining a conditional maintenance reminder:

In this example you want to define a maintenance message that will remind the operator, every morning when starting-up the system, to check the system liquid level (full), liquid waste and tip waste levels (empty).

To do this:

1. Click on the **Add Job** button to define a new maintenance job.
2. In the **is true then run job** field enter the general name of the maintenance reminder you want to define, e.g. "General level checking prompt". This text is automatically entered in the maintenance jobs list.
3. Click on the **Add Task** button to define the task(s) included in this maintenance job. This opens the **Add Maintenance Task** dialog.
4. Select **Display message** and click on the **OK** button. This opens the **Display Message Task** dialog.
5. In the blank space, enter the text of the message prompt. For example, enter: "Please check that the system liquid container is full, that the liquid waste container is empty and that the tip waste container is empty."
6. Click on the **OK** button to close this dialog and go back to the main **Maintenance** tab.
7. Now you have to specify when this message prompt should be displayed. To do this, click on the **Insert Function** button. This opens the **Insert Function** dialog.
8. In the current example, you want to specify that the message prompt should be displayed every day upon start-up. Define the condition ("Days>=1") in the **If** edit box by using the **Insert Function** dialog (e.g. "Days") and the keyboard (for ">=1").
9. When done, click on the **OK** button to confirm and close the **Maintenance** tab.

Now every morning when you start-up your **Elisys Duo** instrument, the entered prompt is displayed.

## Example 2

### Defining an automated maintenance task

In this example you want to predefine an additional "Purge washer routine" that can be launched easily when needed (e.g. after using specific wash buffers...).

To do this:

1. Start as described in the previous example. In the **is true then run job** field enter "Purge washer routine".
2. When you get to the **Add Maintenance Task** dialog, select **Purge washer** and click on the **OK** button.
3. You are then prompted to specify from which container and with how much liquid you want to purge the washer (e.g. "Red" container for Clean fluid and "10 ml/tip").  
It is possible and advantageous to define additionally a display message to inform the use about the function of this maintenance job (see example 1 and complex jobs).
4. When done, click on the **OK** button to confirm and close the **Maintenance** tab.

In this case, you have defined the task but you have not defined a condition upon which the system would automatically perform the maintenance routine. You must start this maintenance job manually.

## Complex Jobs

### More elaborate maintenance routines:

From these two relatively simple examples, you can program all sorts of more complex maintenance checklists or conditional routines such as:

- Start-up checklist: add several consecutive "Display message" tasks and a "Days>=1" condition.

- Weekly maintenance routine reminder: condition "Days>=7".
- Prime / Purge routine if the system has not been used for over 2 weeks: condition "Days>=15 AND Worklists=0".
- Empty tip waste reminder if 900 or more tips have been used: condition "Tips>=900".
- Rinse all four washer lines: combine messages to prompt user to fill all four wash containers with rinse fluid and 4 purge washer tasks, one for each container/washer line. End with a message.
- Etc.



---

*Note however that the maintenance status and conditions are checked only each time the instrument is initialized. So, if, for example, you define a message to remind you to empty the tip waste container when you have used more than "n" tips, the message will not be displayed as soon as tip "n + 1" is used but only the next time the instrument is initialized (i.e. upon start-up or when a selftest is performed).*

---

### Log and Skip

#### Logged maintenance jobs / skipped maintenance jobs

Each time you perform (or allow the system to execute) a predefined maintenance routine, this is recorded in the log file.

The log file also keeps track of all cases where the operator was prompted to execute a conditional routine but decided to skip it.

In the log file, performed routines are displayed in black, skipped routines in red.

A required maintenance routine can only be skipped by the operator if the person who defined it selected the **User can skip job** checkbox in the **Maintenance** tab.

## 8 Maintenance and Cleaning

In order for it to operate correctly, it is essential that the **Elisys Duo** system be maintained in accordance with the maintenance plan and procedures described below.

### 8.1 Safety and Hints about Cleaning/Decontamination



***Follow all safety instructions before servicing the instrument (see figure 1.3 on page 1-7) to avoid personal injuries and material damage!***



***Defect or leaky tubes, syringes, valves or pumps lead to deterioration of the pipetting results and consequently corruption of final results. Furthermore incorrectly flushed tips can cause mixing up of sample material.***



***Instrument could have had contact with infectious material. Pay attention to safety regards! Always wear appropriate gloves, lab coat, and goggles!***



***Dispose of all waste in accordance with legal regulations for biological hazardous waste (see figure 1.3.8 on page 1-11).***



***Please follow closely the steps contained in the individual instructions to achieve a perfect function of the instrument.***



***Disinfectants must not come into contact with bearings and guides, as otherwise the greasy film may dissolve!***



***Disinfectants must not be used in the vicinity of circuit boards, light barriers and Plexiglas surfaces!***



***Take care not to touch any optic surfaces (e. g. scanners, lenses, sensors)!***

## Maintenance and Cleaning

### Safety and Hints about Cleaning/Decontamination



*The operator may only perform the maintenance work described in this manual.*



*Only clean the glass pane of the bar code scanner with a softy and lint-free cloth. Do not use any aggressive detergents (e.g. acetone).*



*We recommend Gigasept<sup>®</sup>, Liquinox<sup>®</sup> or Rivascope<sup>®</sup> to decontaminate the instrument. Do not use the decontamination liquid undiluted!*



***Pay attention to manage the decontamination products, because they are harmful as indicated on the bottle. Read the instructions of the decontamination products before use.***



*Do not use bleach or decontamination liquid with alcohol!*



*Use soft clothes with neutral detergent or with ethanol may to clean the touch screen. Do not use any chemical solvent, acidic or alkali solution. Do not allow liquid from soaking into the joint of film and glass which may result in peeling or malfunctioning.*



***DO NOT*** autoclave containers or parts of the instruments!

Spare wash buffer bottles (with normal caps) can be ordered. Having spare bottles allows you to remove your partially full bottles from the instrument and to store them directly while performing the cleaning procedure with the spare bottles (instead of having to transfer the buffer into storage containers at night and re-transfer it back into the bottles later).

When the instrument is turned off, mobile modules such as the pipettor guide rail or the plate transport unit may be moved manually so as to get better access to certain parts of the instrument. This is to be done as gently as possible so as not to damage or misalign the modules.

## 8.2 Daily Maintenance

### 8.2.1 Start-Up

	Maintenance	Power	See also
System liquid container	Check the level of system liquid in the system liquid container. If low, refill it.	OFF	chapter 2.2.8.2 on page 2-15
Waste liquid container	Check the level of waste liquid in the waste liquid container. If full or nearly full, empty and decontaminate it. Dispose waste liquid in accordance with legal regulations for biological hazardous waste.	OFF	-
Pipettor	Check pipettor tubing and syringe for air bubbles or leakages as these can cause pipetting errors.	OFF	chapter 8.6.1 on page 8-11, chapter 8.6.2 on page 8-11

Table 8-1: Daily maintenance: Start-up

## 8.2.2 After Each Run

	Maintenance	Power	See also
Inspect instrument	Inspect instrument deck, plates, racks, etc. for spillages. If there are spillages, check instrument for leakages.	ON	chapter 8.6.1 on page 8-11, chapter 8.6.2 on page 8-11
Remove racks	Remove sample and reagent racks. Dispose tubes and bottles in accordance with legal regulations for biological hazardous waste.	ON	chapter 4.10.2 on page 4-69, chapter 4.10.3 on page 4-69
Remove plates	Unload used test and dilution plates. Dispose plates in accordance with legal regulations for biological hazardous waste.	ON	chapter 4.10.1 on page 4-67, chapter 4.10.4 on page 4-70
Waste bag for disposable tips	Check the waste bag for disposable tips. If full or nearly full, replace it. Dispose the waste bag in accordance with legal regulations for biological hazardous waste.	ON	-
System liquid container	Check the level of system liquid in the system liquid container. If low, refill it.	ON	chapter 2.2.8.2 on page 2-15
Waste liquid container	Check the level of waste liquid in the waste liquid container. If full or nearly full, empty and decontaminate it. Dispose waste liquid in accordance with legal regulations for biological hazardous waste. <b>Observe all safety notes and hints about cleaning/decontamination</b> (see chapter 8.1 on page 8-1).	ON	-

Table 8-2: Daily maintenance: After each run



## 8.2.3 Shut Down

	Maintenance	Power	See also
Inspect instrument	Inspect instrument deck, plates, racks, etc. for spillages. If there are spillages, check instrument for leakages.	ON	chapter 8.6.1 on page 8-11, chapter 8.6.2 on page 8-11
Remove racks	Remove sample and reagent racks. Dispose tubes and bottles in accordance with legal regulations for biological hazardous waste.	ON	chapter 4.10.2 on page 4-69, chapter 4.10.3 on page 4-69
Remove plates	Unload used test and dilution plates. Dispose plates in accordance with legal regulations for biological hazardous waste.	ON	chapter 4.10.1 on page 4-67, chapter 4.10.4 on page 4-70
Close worklists and files	Close all finished worklists and opened file (assay files, result files...).	ON	chapter 3.1.2 on page 3-3
Exit user software	Close the <b>Elisys Duo</b> software (select the File > Exit menu item).	ON	-
Shut down windows	Shut down windows	ON	-
Switch off	Switch off the instrument	OFF	-
Waste bag for disposable tips	Check the waste bag for disposable tips. If full or nearly full, replace it. Dispose the waste bag in accordance with legal regulations for biological hazardous waste.	OFF	-
System liquid container	Check the level of system liquid in the system liquid container. If low, refill it.	OFF	chapter 2.2.8.2 on page 2-15
Waste liquid container	Check the level of waste liquid in the waste liquid container. If full or nearly full, empty and decontaminate it. Dispose waste liquid in accordance with legal regulations for biological hazardous waste. <b>Observe all safety notes and hints about cleaning/decontamination</b> (see chapter 8.1 on page 8-1).	OFF	-
Disposable tip racks	Unload disposable tip racks. Partially used tip racks may remain on the instrument overnight (particularly if you are using the "Re-use partially used racks" option (see chapter 4.7.6 on page 4-42).	OFF	-

## Maintenance and Cleaning

### Daily Maintenance

	Maintenance	Power	See also
Reagent and control bottles	<p>If they are not empty and can be re-used, remove the reagent and control bottles from the racks or instrument, close them (be careful not to mix the caps!) and store them in a refrigerator. Otherwise, dispose of them in accordance with legal regulations for biological hazardous waste.</p> <p><b>Note:</b> Do not store racks in a refrigerator!</p>	OFF	-
Inspection/Cleaning/Decontamination	<p>Every evening after shut down, inspect the instrument for stains or spills. Make sure to inspect all individual surfaces, compartments and work areas:</p> <ul style="list-style-type: none"><li>• Outer surfaces, particularly around the handle of the cover.</li><li>• Open the cover to check the upper work areas.</li><li>• Pipettor wash station</li><li>• Sample and reagent unit</li><li>• Make sure no tips have remained blocked in the waste slide (ramp). If necessary, pull out the slide to do so.</li><li>• Do not forget to check for liquid underneath the wash buffer bottles.</li></ul> <p>If you detect stains, small spills or areas that are generally dirty, decontaminate them (see chapter 8.3 on page 8-7).</p> <p><b>Observe all safety notes and hints about cleaning/decontamination</b> (see chapter 8.1 on page 8-1).</p>	OFF	-

Table 8-3: Daily maintenance: Shut down

## 8.3 Weekly Maintenance

	Maintenance	Power	See also
Washer cleaning/decontamination	<p>Clean the wash head with the cleaning needle.</p> <p>Use an assay to decontaminate and flush the washer.</p> <p>Procedure:</p> <ol style="list-style-type: none"> <li>1. Fill <b>diluted</b> decontamination liquid into an empty wash buffer bottle.</li> <li>2. Fill deionised water into a second empty wash buffer bottle.</li> <li>3. Start an assay which first use the <b>diluted</b> decontamination liquid and after that the deionised water.</li> <li>4. After the run, remove the bottle with <b>diluted</b> decontamination liquid and put the bottle with deionised water to this washer channel.</li> <li>5. Start a second assay to rinse the channel tubings.</li> <li>6. After the second run, empty and clean all wash buffer bottles.</li> </ol> <p><b>Observe all safety notes and hints about cleaning/decontamination</b> (see chapter 8.1 on page 8-1).</p>	ON	chapter 8.6.4.1 on page 8-14 -
Daily maintenance	Perform the shut down steps of the daily maintenance.	-	chapter 8.2.3 on page 8-5

## Maintenance and Cleaning

### Weekly Maintenance

	Maintenance	Power	See also
Instrument and accessories cleaning/decontamination	<p>Clean and decontaminate all individual surfaces, compartments, work areas and accessories:</p> <ul style="list-style-type: none"><li>• Outer surfaces.</li><li>• All work areas.</li><li>• Pipettor wash station</li><li>• Tip eject station</li><li>• Loading bay</li><li>• Loading bay bar code scanner</li><li>• Waste slide (ramp)</li><li>• Plate transport module</li><li>• Do not forget to check for liquid underneath the wash buffer bottles.</li><li>• Touch screen (only with soft clothes with neutral detergent or with ethanol)</li><li>• Racks</li><li>• Plate carriers</li></ul> <p><b>Observe all safety notes and hints about cleaning/decontamination</b> (see chapter 8.1 on page 8-1).</p>	OFF	-

Table 8-4: Weekly maintenance

## 8.4 Monthly Maintenance

	Maintenance	Power	See also
Weekly maintenance	Perform the weekly maintenance.	-	chapter 8.3 on page 8-7
Instrument and accessories cleaning/decontamination	<p>Clean and decontaminate all individual surfaces, compartments, work areas and accessories:</p> <ul style="list-style-type: none"> <li>• Wash buffer bottles. Clean the bottles only, not the caps and sensor devices.</li> <li>• System liquid container. Inspect the filter in the cap.</li> <li>• Use a soft lint-free cloth, moistened with ethanol, to gently clean the head of the pipettor. Allow to dry.</li> </ul> <p><b>Observe all safety notes and hints about cleaning/decontamination</b> (see chapter 8.1 on page 8-1).</p>	OFF	-
Performance evaluation	Check the performance of the pipettor on regular basis using qualified kits.	ON	-

Table 8-5: Monthly maintenance

## 8.5 Maintenance Jobs

As part of its normal operating routine, the **Elisys Duo** system performs a number of maintenance jobs automatically. For example:

- During each selftest (see chapter 5.1 on page 5-1), the system checks the status of all instrument modules.
- During each run, the pipettor is primed with system liquid.
- Following each wash step, the washer is purged with clean fluid (deionised water).

These maintenance jobs are controlled automatically without any user intervention. But the **Elisys Duo** system also includes a feature allowing users to predefine some maintenance tasks and maintenance reminders (see chapter 7.2.8 on page 7-34).

Some of this predefined maintenance tasks will start automatically, if a special condition is fulfilled. But you can also this and all other predefined maintenance tasks start manually.

If you want to start this predefined maintenance task:

1. Click on the **Utilities** button.
2. Select the **Maintenance** symbol.



*Figure 8-1: System Maintenance dialog with examples*

3. Select the desired maintenance job.
4. Click on the **Execute** button.
5. Click on the **Yes** button to start the maintenance job.
6. Follow the job information.

## 8.6 Special Maintenance Procedures/ Emergencies

This section describes maintenance procedures that are not to be performed on a regular basis but as needed depending on events/incidents affecting the instrument or its environment.

On emergency stop (cancelling a run) and emergency test plate removal, see chapter 4.8.7 on page 4-57 and chapter 5.5.3 on page 5-38.

### 8.6.1 Visually Check Tubing



***Defect or leaky tubes, syringes, valves or pumps lead to deterioration of the pipetting results and consequently corruption of final results. Furthermore incorrectly flushed tips can cause mixing up of sample material.***

Make sure all tubing is in good condition and properly connected to connectors.



1. Switch the **Elisys Duo** System off.
2. Disconnect main power from the system.
3. Check all tubing connections accurately.
  - If they are poor or loose tighten them properly.
4. Check tubing for any signs of wear or leaking.
  - Call service to change wear or leaking tubing.
5. Make sure tubing insides are clean and free from any deposits, residue or clogs.
  - If the tubing seems to have residue, deposits or air bubbles flush the system.  
If necessary decontaminate the system as described in the decontamination procedures.
  - If there are furthermore any deposits, residue or clogs, call service to change the tubing.

### 8.6.2 Visually Check Syringe and Three-Way-Valve



***Defect or leaky tubes, syringes, valves or pumps lead to deterioration of the pipetting results and consequently corruption of final results. Furthermore incorrectly flushed tips can cause mixing up of sample material.***



1. Switch the **Elisys Duo** System off.
2. Disconnect main power from the system.
3. Check if all syringes connections accurately.
  - If they are poor or loose tighten them properly by hand.

## Maintenance and Cleaning

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### Special Maintenance Procedures/Emergencies

- Syringes have to be leak free and clean.
  - If they are leaking or the glass barrel is scratched call service to change it.
4. Check in all valves connections accurately.
- If after inspecting of the liquid paths, dripping is observed at the end of a tip adapter, the valve may require replacement.
  - Call service to change the valve.



### 8.6.3 Heavy Liquid Overflow

In case liquid overflows into the instrument modules while the system is running:



1. Switch off the **Elisys Duo** instrument immediately.
2. Disconnect the power cord.
3. Using absorbent paper, clean-up all excess liquid.
4. Make sure to check all areas that may have been affected. Unload the racks from the sample and reagent units, check the various modules (including incubators, photometer).
5. Dispose of used absorbent paper in accordance with legal regulations for biological hazardous waste.
6. Decontaminate the affected areas as described in the maintenance sections.
7. Allow to dry.
8. Before turning the system on again, identify the source of the problem (damaged tubing, faulty washer...) and take appropriate actions. If in doubt, call your service engineer.

The procedure is identical if the liquid overflow is noticed only some time after the incident has occurred. Even if the instrument is already turned off, do not forget to disconnect the power cord.

## **8.6.4 Washer Malfunction**

### **8.6.4.1 Cleaning a Clogged Wash Head**



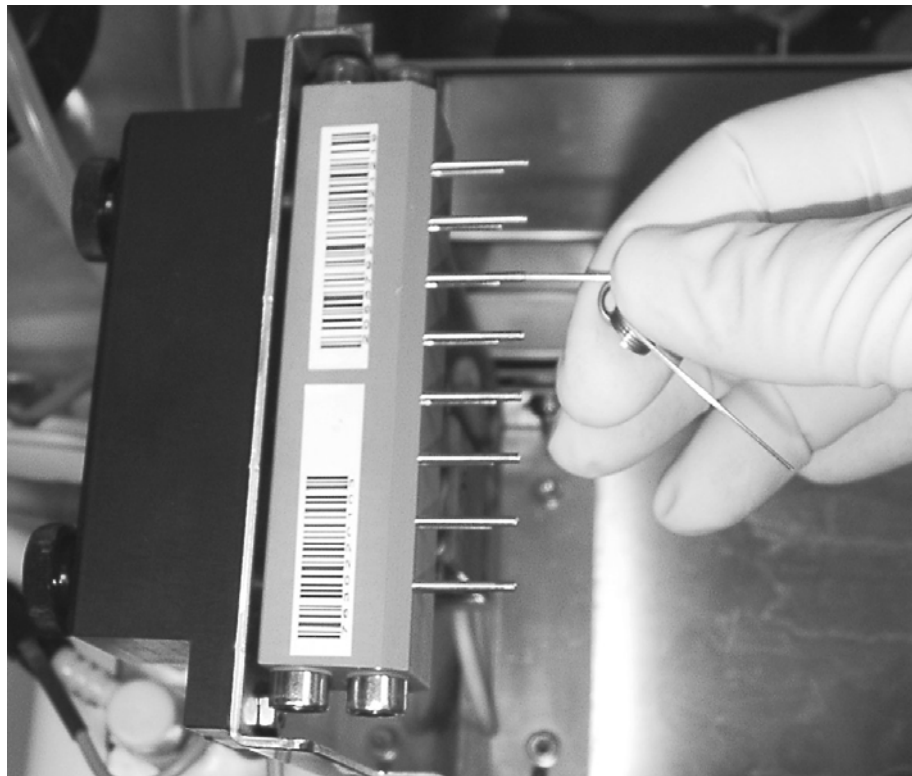
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***The wash head could have had contact with infectious material. Pay attention to safety regards! Always wear appropriate gloves, lab coat, and goggles!***

---

If the wash function is not longer adequate, you have to clean the needles of the wash head.

1. Open the service cover of washer (6), see chapter 2.1.2 on page 2-3 and remove it.
2. Using the supplied cleaning needle, clean the 8 dispense and the 8 aspirate needles of the wash head.



*Figure 8-2: Cleaning the wash head needles*

3. Install the service cover of washer (6).

### **8.6.4.2 Other Problems**

If you have performed all the above actions but the washer still does not operate correctly, other parts such as filters or pumps may be involved. Call your service engineer for assistance.

## 8.6.5 Power Supply Malfunction

### 8.6.5.1 Power Cuts/Outages

If a power cut occurs during a run, the system can rely on a recovery file to resume the run automatically when the power cut is over.

When the power supply is reset, the **Elisys Duo** system will normally prompt you to continue the run from where it was interrupted (your decision to continue the run will depend on the duration of the power cut). Note however that if only a part of a plate has been processed, the system does not keep track of the sample locations and you may have to reselect the samples to be tested.

If the power cut occurs outside a run, turn off the instrument.

If you frequently experience power supply fluctuations, it is recommended that you install a UPS (Uninterruptible Power Source) device to protect your **Elisys Duo** system.

### 8.6.5.2 Replacement of Main Fuses



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***Spare fuses must match the values (nominal voltage, nominal current, and type) specified by the manufacturer. Always replace blown fuses, do not try to repair them. Never short-circuit the fuse holder.***

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The **Elisys Duo** instrument operates with (two) fuses that are located in a fuse holder at the right side of the instrument, just above the power supply cord (see chapter 2.1.4 on page 2-6 - 23).

If the instrument does not power on when you press the ON/OFF switch, the power fuses may be blown. Spare fuses are supplied with the instrument or can be purchased (see chapter 12.1 on page 12-1).

To replace a blown fuse:



1. Switch off the system.
2. Disconnect main power from the system.
3. Pull out the fuse carrier with a screw driver.

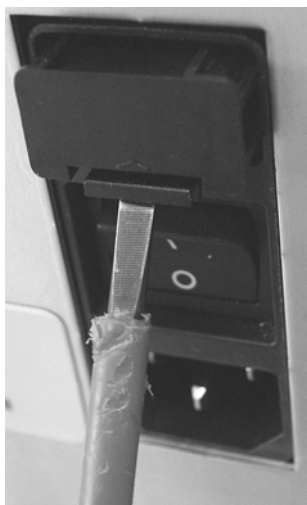


Figure 8-3: Fuse carrier

4. Change the faulty fuse(s):  
**Fuse: 3.2 A T, 250 V**

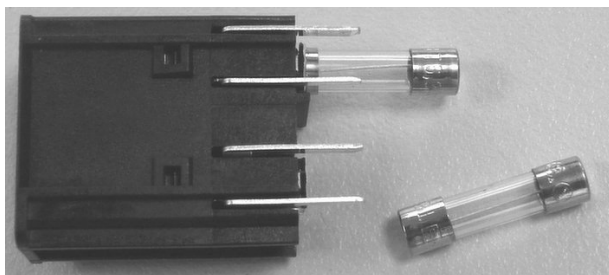


Figure 8-4: Fuse carrier with fuses

5. Insert the fuse carrier.
6. Connect the main power.
7. Switch on the system.



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*Although spare fuses are provided with the instrument and the replacement procedure is described above, you should be aware that blown fuses are very often indicators of other malfunctions that may be affecting instrument modules, components or wires. If in doubt or if the fuse blows again shortly after you have replaced it, please call your service engineer for assistance.*

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## 8.6.6 Photometer Malfunction

### 8.6.6.1 Replacement of Photometer Lamp



***Module uses halogen lamp, it will be hot even after short periods of use and takes time to cool down. Handle with care!***



***Take care not to touch any optical surfaces (e. g. bulb, mirror)!***

In the event of a lamp failure, replace the lamp with the recommended part only. Use of other lamps is not acceptable.

#### Removal



1. Shut down the computer and switch off the system.
2. Disconnect main power from the system.
3. Remove both retaining screws (2) and the photometer service cover (1).



Figure 8-5: Photometer service cover

4. Lift the lamp retaining clip (3) and remove the lamp (4).

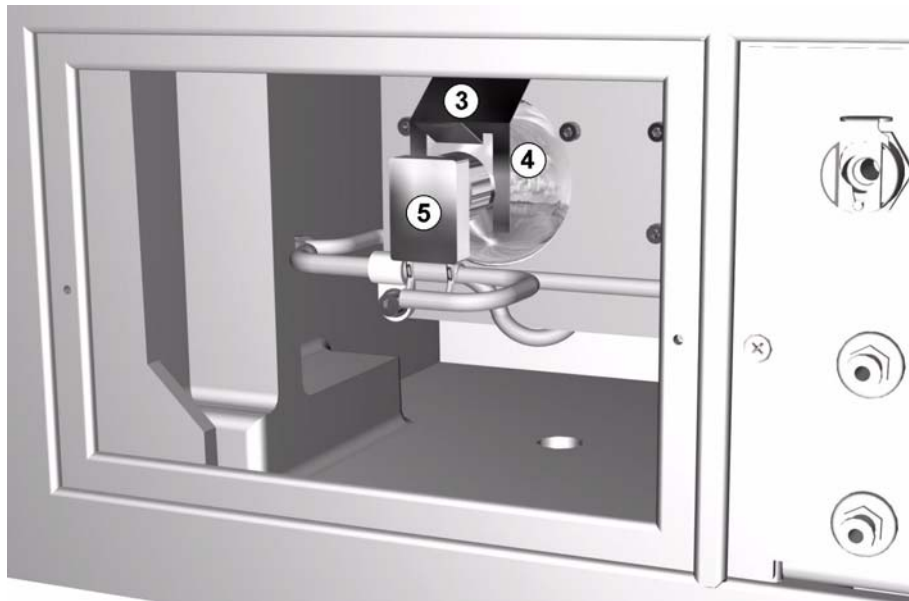


Figure 8-6: Photometer lamp

5. Disconnect the lamp connector (5).

### Installation

6. Plug the new lamp (4) into the lamp connector (5).
7. Lift the lamp retaining clip (3) and insert the lamp (4).
8. Install the photometer service cover (1) and tighten both retaining screws (2).
9. Execute the verification plate process to verify the new lamp.

## 8.7 Damaged Parts

In most cases, repairing and/or replacing damaged parts will require the assistance of your service engineer. If in doubt, please call before trying to repair/change the part yourself.

However, two specific cases need to be mentioned.

### **Parts damaged during shipment:**

If you have ordered parts that are shipped directly to you, examine them carefully when unpacking. Although they are packed to provide maximum protection, damage can occur. In this case, report the damage in the first place to the carrier/shipping company and then to the supplier.

### **Decontamination:**

If you want to return damaged parts to your local supplier (e.g. if under guarantee), please note that the parts must be decontaminated first. Follow the maintenance procedures to decontaminate the instrument and accessories (see chapter 8.2 on page 8-3, chapter 8.3 on page 8-7, and chapter 8.4 on page 8-9).





# 9 Troubleshooting and Error Messages

## 9.1 Error Messages

If the **Elisys Duo** does not work, this is often due to minor problems which you can deal with yourself.

This chapter describes error messages and gives instruction on error recovery.

System messages appear in the status bar of the **Elisys Duo** software, error messages are displayed in a separate window, which has to be confirmed. Some of that messages are also written into the result report.

'%1' and '%2' are place holders for a system module or the designation of a plate, a reagent or an error number.

Error message:	Cause:	Action:
<b>A result file already exists for plate "xxxx"</b>	The system will automatically generate a result file not for each worklist but for each plate included in a worklist. This result file will be named after the Plate ID displayed in the <b>Load Plate</b> dialog (e.g. "HBc01.res"). Therefore, if you choose a Plate ID that has already been used in a former worklist, when you click on the <b>OK</b> button, the system will display this warning message.	Unless you specifically want to overwrite the former result file, click on the <b>No</b> button and go back to the <b>Load Plate</b> dialog to change the Plate ID. To do so just delete the name shown in the Plate ID field and enter a new name. Therefore, when choosing a Plate ID, try to find a precise name that will differentiate each test from previous or future tests. Do not retain the "Plate 1", "Plate 2"... default ID and do not enter just the test ID "HBc", "HIV", etc. The system does not expect any specific format so any chain of alphanumeric characters (with or without blank spaces) can be entered.  To replace the existing result file, click on the <b>Yes</b> button. Note that the overwritten result file will be lost.
<b>ABORT button pressed</b>	The <b>Stop</b> button has been clicked during a run.	The run has been interrupted and may be continued or aborted completely (see chapter 4.8.7 on page 4-57).
<b>Aborting plate ...</b>	The operator clicked the <b>Stop</b> button during a run and then, in the <b>Pause</b> dialog, requested that the processing of one or more plates be aborted	You can decide to resume the run for the remaining plates or abort it completely (see chapter 4.8.7 on page 4-57).
<b>Argument error in command</b>	During initialization procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the concerning module. If error recurs the PCB of concerning module has to be checked.

## Troubleshooting and Error Messages

### Error Messages

Error message:	Cause:	Action:
<b>Aspirate check failed for reagent %1</b>	<p>During the run. Aspirate step of reagent was faulty.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> <li>Incorrect tracking due to wrong bottle type.</li> </ul>	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li><b>Retry</b> button: Pipettor will dispense back the aspirated liquid and repeats the aspirate step.</li> <li><b>Abort Plate</b> button: Plate will be aborted.</li> <li><b>Continue</b> button: System goes on but all concerning samples will be flagged.</li> </ul> <p><b>Troubleshooting:</b></p> <ul style="list-style-type: none"> <li>Check, if correct bottles were used.</li> <li>If error recurs, call service to check the teaching.</li> </ul>
<b>Barcode IC error</b>	The bar code cannot be read.	<p>Verify the readability of the bar codes. Select the <b>Utilities &gt; System Set-up</b> menu item, click on the <b>Sample Rack</b> tab and check the bar code parameters (see chapter 7.2.5.2 on page 7-28).</p> <p>Try reading the bar codes once more (withdraw and insert your rack again). If this attempts fail, call your service engineer.</p>
<b>Clot detected in sample %1</b>	<p>During the run. Clots were detected in sample %1.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> <li>Deficient sample preparation</li> <li>Incorrect tracking due to wrong sample rack type</li> <li>Incorrect tracking due to wrong tube diameter</li> <li>Tip touches the (wet) wall of a tube.</li> </ul>	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li><b>Skip Sample</b> button: system will skip the concerning sample and will go on with the work list.</li> <li><b>Abort Plate</b> button: plate will be aborted.</li> <li><b>Continue</b> button: system goes on but concerning sample will be flagged.</li> </ul> <p><b>Troubleshooting:</b></p> <ul style="list-style-type: none"> <li>Check, if correct tubes were used.</li> <li>If error recurs, call service to check the teaching.</li> </ul>
<b>Clot detected in reagent ...</b>	Clots were detected in the respective reagent.	Pause the run (see chapter 4.8.7 on page 4-57) and replace reagent.
<b>Colorimeter A/D error</b>	During the initialization procedure or during a run. Error of the analog/digital converter of the photometer.	Please, restart the system. If the error recurs, call service to check the photometer module.

Error message:	Cause:	Action:
<b>Colorimeter A/D over range error</b>	During the initialisation procedure or during a run. Upper limit of analog/digital converter of the photometer has been exceeded due to the signal height of the pre-selected resolution.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: System will try to repeat the last step.</li> <li>• <b>Ignore</b> button: Not advisable cause system cannot go on without sequence errors.</li> </ul> <p>Push the <b>Retry</b> button, if the error recurs, abort the work list and check the filters and the photometer lamp.</p> <p><b>Troubleshooting:</b></p> <p>If error recurs after checking the filters and the lamp, call service to check the whole photometer module.</p>
<b>Colorimeter A/D under range error</b>	During the initialisation procedure or during a run. Too less light reaches the electronic of photometer.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: System will try to repeat the last step.</li> <li>• <b>Ignore</b> button: Not advisable cause system can not go on without sequence errors.</li> <li>• <b>Abort</b> button: The work list will be aborted.</li> </ul> <p>Press the <b>Retry</b> button. If the error recurs, abort the worklist. The whole photometer module has to be checked.</p> <p><b>Troubleshooting:</b></p> <p>The halogen lamp of the photometer is faulty and has to be replaced. If the error persists, the optical components in the photometer (filter, upper or lower optic block) may be dirty. Call service to clean or replace the photometer.</p>
<b>Colorimeter back-grounds out of range</b>	During the initialisation procedure or during a run. Typically occurs when light entered the measurement chamber.	<p>Restart the software to initialise the photometer again. Please check if the photometer cover, all instrument sheet metal covers and the deck top are installed correctly and all filters are installed.</p> <p>If the error recurs, please call service.</p>
<b>Colorimeter EEPROM error</b>	During the communication between colorimeter and PC.	<p>Initialize the module again. If the error recurs the photometer board has to be checked, please call service.</p>
<b>Colorimeter invalid filter %1 error</b>	During initialisation procedure. The gain factor for the respective filter cannot be identified.	<p>Restart the software to initialize the photometer again, after checking the filter configuration.</p> <p>If error recurs, change the concerning filter, please call service.</p>

## Troubleshooting and Error Messages

### Error Messages

Error message:	Cause:	Action:
<b>Colorimeter filter motor home error</b>	During the initialisation procedure. The system does not recognize the current position of the filter motor.	Restart the software. If the error recurs, the filter wheel has to be checked, please call service.
<b>Colorimeter filter motor movement error</b>	During the initialisation procedure. The movement of the filter wheel is faulty.	Restart the software. If the error recurs, the filter wheel has to be checked, please call service.
<b>Colorimeter lamp error</b>	During the initialisation procedure. Halogen lamp of photometer is faulty.	Replace halogen lamp and restart the software to initialise the photometer again.
<b>Colorimeter optic channel %1 error</b>	During the initialization procedure. One of the optical channels is faulty.	The lower or upper optic blocks have to be cleaned, or the fibre has to be replaced, please call service.
<b>Colorimeter positioning error</b>	Plate movement is faulty.	If the error recurs, call service to check the plate transport teaching of the reader position, the guide rails and the plate carriers.
<b>Command execution error</b>	During initialization procedure. Faulty firmware is installed.	Please call service to reinstall the firmware for the concerning module.
<b>Command not implemented</b>	During initialization procedure. Faulty firmware is installed.	Please call service to reinstall the firmware for the concerning module.
<b>COMGEN error '%1'</b>	At start-up. Cable connection between PC board and instrument CU board is faulty.	Start instrument again. If this error recurs, call service.
<b>COP serial port test error</b>	At start-up. Error in serial interface on instrument CU board.	Start instrument again. If error recurs, the instrument CU board has to be replaced, call service.
<b>Crash cover file detected.</b> <b>Do you want to try and recover the work list?</b>	After power failure.	<p><b>Warning: It is not recommended to use the crash recovery. Any results produced in a recovered run be discarded.</b></p> <p>Details on recovery procedure: Message: "Do you want to try and recover the work list?"</p> <ul style="list-style-type: none"> <li><b>No</b> button: Software continuous with initialising the system. Old work list will be deleted.</li> <li><b>Yes</b> button: The following message appears: "Is the system still running?" <ul style="list-style-type: none"> <li><b>No</b> button: The system initialising first the modules before continuous the next work list step.</li> <li><b>Yes</b> button: The systems continuous with the next work list step.</li> </ul> </li> </ul>

Error message:	Cause:	Action:
<b>Disposable tip dropped</b>	<p>The disposable tip has fallen off the adaptor unexpectedly.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> <li>Defective tip</li> <li>Insufficient tip pick-up force due to excessive friction inside the z drive</li> <li>Insufficient tip pick-up force due to excessive flexibility in the tip tray or deck top.</li> </ul>	<p>The user should pick up the dropped tip, check for possible contamination and for what could have caused the problem and select the appropriate recovery option. <b>Warning: Especially, if the error occurred while the pipettor was moving across any wells, vials or tubes, the affected plate must be aborted.</b> The error is logged in the event log.</p> <p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li><b>Retry</b> button: The system will repeat the pipetting step where the error occurred after initialisation of the pipettor arm.</li> <li><b>Abort Plate</b> button: The whole plate will be aborted.</li> <li><b>Ignore</b> button: The concerning sample will be flagged. System goes on with the next pre-dilution.</li> </ul>
<b>Drive not moving</b>	Motor error in scanner of reagent and sample rack. Scanner firmware does not work correctly. Electrical or mechanical problems of scanner.	If error occurs please use the possibility to allocate the reagents and samples, manually. The bar code scanner of the loading bay has to be checked, please call service.
<b>Duplicate patient ID .....!</b> <b>Edit the patient IDs so that only one tube is used per patient.</b>	Two loaded sample tubes with identical bar codes.	Remove the sample tubes and use an other bar code for one of this tubes (see chapter 9.2.1.9 on page 9-18).
<b>Error: Argument error in '%1'</b>	During the initialization procedure. Component can not be actuated.	Restart software and analyser. If the error recurs, the concerning module has to be checked, please call service.
<b>Error during assay layout reduction. Reduce the number of samples. Check that the assay layout is reducible.</b>	After adding assay and patient to the plate. Too many samples are used on this plate.	Push the OK button and reduce the numbers of patients, that a maximum of 96 wells on one plate are used.
<b>Error opening file ...</b>	Error during reading or writing a file (network down or directory moved/deleted).	Check or change the target directory in the <b>Directories</b> tab of the <b>Options</b> dialog (see chapter 7.1.6 on page 7-8).
<b>Error scheduling plate '...'</b>	After adding plate and assay. The assay programming is not correct or the combination of different plates can not be scheduled.	Push the OK button and modify the assay or work list.
<b>Illegal parameter (length/type)</b>	During initialization procedure. Faulty firmware is installed.	Please call service to reinstall the firmware for the concerning module.

## Troubleshooting and Error Messages

### Error Messages

Error message:	Cause:	Action:
<b>Incubator heater %1 error</b>	During the initialization procedure or during the run. The heater foil of incubator box %1 is faulty.	The heater foil of concerning incubator box has to be checked, please call service.
<b>Incubator sensor %1 error</b>	During the initialization procedure or during the run. The temperature sensor of incubator box is faulty.	The temperature sensor of concerning incubator box has to be checked, please call service.
<b>Init not reached</b> or <b>Init not in init direction</b>	During initialization procedure of the plate transport (can also be initiated by washer or reader). Error of the plate transport init light barrier or plate transport drive.	Please, restart the software and system.  If the error occurs during a run, please press the <b>Abort</b> button to cancel the worklist. After this error occurs a recovery isn't possible.  If the error recurs the plate transport drive and its init light barrier have to be checked, please call service.
<b>Insufficient volume of pre-dilution %1</b>	During the run. System cannot find enough volume in pre-dilution.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: System will try to repeat the last measurement of level height.</li> <li>• <b>Abort</b> button: The concerning sample will be aborted.</li> <li>• <b>Abort Plate</b> button: The whole plate will be aborted.</li> <li>• <b>Ignore</b> button: The concerning sample will be flagged. System goes on with the next pre-dilution.</li> </ul> <p><b>Troubleshooting:</b></p> <ul style="list-style-type: none"> <li>• Check if the metal plate was put under the dilution plate.</li> <li>• Check if the correct *.mpc file is selected for the pre-dilution plate used.</li> <li>• LLD problems can occur in the pre-dilution plate if liquid with low conductivity is pipetted (e.g. DI water).</li> <li>• The minimal volume that can be detected by the LLD in a well of a dilution plate is 120 µl to 150 µl (depending on the plate used).</li> <li>• Call service to check the teaching of the pre-dilution position.</li> <li>• Call service to double-check the teaching of the *.mpc file used.</li> </ul>

Error message:	Cause:	Action:
<b>Insufficient volume of reagent %1</b>	At reagent check if volume of reagent is insufficient.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Abort check</b> button: reagent check will be aborted. The system goes on with the work list.</li> <li>• <b>Refill bottle</b> button: software jumps back to the loading window where reagents can be filled up.</li> <li>• <b>Continue</b> button: system will go on with checking the next reagent.</li> </ul> <p>To make sure that work list will run without miss pipetting errors, please push <b>Refill bottle</b> and make sure that enough reagent liquid is available.</p> <p><b>Troubleshooting:</b></p> <p>If this error occurs although there is enough liquid provided in the reagent bottle, check if the bottle type used is correct. Call service to check the teaching.</p>
<b>Insufficient volume of sample %1</b>	During the run if volume of sample is insufficient.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: System will try to repeat the last measurement of level height.</li> <li>• <b>Abort</b> button: The sample will be aborted.</li> <li>• <b>Abort Plate</b> button: The whole plate will be aborted.</li> <li>• <b>Ignore</b> button: The concerning sample will be flagged. Systems go on with the next sample.</li> </ul>
<b>Invalid pipettor coordinates on plate X, label sample "...". Check that the dispense labels and aspirate labels are consistent.</b>	After adding plate and assay. The assay programming is faulty. A label of a sample is undefined.	<p>Push the <b>OK</b> button.</p> <p>Modify the assay definition and restart the work list.</p>
<b>Invalid unlock code</b>	During initialization procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the concerning module.

## Troubleshooting and Error Messages

### Error Messages

Error message:	Cause:	Action:
<b>No disposable tips left</b>	During the run. No more tips available or found.	<p>Automatically appearance of the loading window after system message occurs. Load the correct tips to the suggested position. After pushing the OK button the work list will go on.</p> <p><b>Troubleshooting:</b> If this error occurs although there is enough liquid provided in the tube, check if the tube size used is correct. Call service to check the teaching.</p>
<b>No liquid detected for reagent %1</b>	During the run. No liquid for reagent %1 is detected, if reagents check was disabled.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: System will check level of reagent again.</li> <li>• <b>Abort Plate</b> button: Plate will be aborted.</li> <li>• <b>Abort</b> button: The work list will be aborted.</li> </ul> <p>To make sure that the work list will run without miss pipetting errors, push <b>Abort</b> and enable the <b>Reagent check</b> in the panel options. After that, you have to start the work list again. The old work list cannot be recovered.</p>
<b>No liquid detected for sample %1</b>	During the run. No liquid for sample %1 is detected, if sample check was disabled.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: System will check level of sample again.</li> <li>• <b>Ignore</b> button: System goes on but concerning sample will be flagged. <b>Note: air can be pipetted if you will push the Ignore button.</b></li> <li>• <b>Abort Plate</b> button: Plate will be aborted.</li> <li>• <b>Abort</b> button: The concerning sample will be aborted.</li> </ul>
<b>No response to command '%1'</b>	System cannot communicate with PC.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: PC will try to connect to system again.</li> <li>• <b>Abort</b> button: the work list will be aborted.</li> </ul> <p>If error message recurs after pushing <b>Retry</b>, restart the system.</p> <p><b>Troubleshooting:</b> Check the cable between PC board COP. Please call service to check the electronics.</p>



Error message:	Cause:	Action:
<b>Open loop error at tip eject</b>		<p>Remove tip manually from pipettor or trigger eject mechanism manually. Press the <b>OK</b> button after removing the tip manually. Press <b>Retry</b>. The system logs the failure in the event log and goes on with the next step.</p> <p>If the error recurs call service to check the teaching and the friction force of the Z drive</p>
<b>Parameter not allowed/found</b>	During initialization procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the concerning module.
<b>Pipettor error 0X0E-LY (or LX) position not reached</b>	During a pipettor movement. Pipettor crashes or mechanical problems.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: After initialisation, the system will try to reach the position again.</li> <li>• <b>Ignore</b> button: Not advisable cause system cannot go on without sequence errors.</li> <li>• <b>Abort</b> button: The work list will be aborted.</li> </ul> <p><b>Troubleshooting:</b></p> <p>Push the <b>Retry</b> button to repeat the last step. After pressing <b>Retry</b>, press the <b>Resume</b> button to continue work-list. If the error recurs please open system flap and check if they're any obstacles that disturb the pipettor movement. If there are no obstacles, the pipettor module has to be checked, please call service.</p>
<b>Pipettor open loop / overload error</b>	Pipettor crash during a run.	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: After initialisation, the system will try to repeat the former pipetting step.</li> <li>• <b>Ignore</b> button: System will continue with the next pipetting step.</li> <li>• <b>Abort</b> button: The whole plate will be aborted.</li> </ul> <p><b>Troubleshooting:</b></p> <p>Push the <b>Retry</b> button to repeat the last step. After pressing <b>Retry</b>, press the <b>Resume</b> button to continue work-list. If the error recurs please open system flap and check if they're any obstacles that disturb the pipettor movement. If there are no obstacles, the pipettor module has to be checked, please call service.</p>

## Troubleshooting and Error Messages

### Error Messages

Error message:	Cause:	Action:
<b>Plate not detected</b>	<p>During plate transport movement. A plate carrier is not detected where it is expected.</p> <p>Possible reasons for the error</p> <ul style="list-style-type: none"> <li>• Wrong teaching</li> <li>• Plate carrier does not interrupt a "plate in" light barrier in an incubator (or room temperature) slot: Defective light barrier, tolerance issue in the room temperature slots with the guiding rails (try to push the guiding rails farther to the back or exchange the plate carrier). Defective shake mechanism.</li> </ul>	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: Plate transport will try to load / unload the plate again.</li> <li>• <b>Ignore</b> button: Not advisable cause system cannot go on without sequence errors.</li> <li>• <b>Abort</b> button: System will try to abort the plate.</li> </ul> <p><b>Troubleshooting:</b></p> <p>Plate transport and incubator slots must be checked, please call service.</p>
<b>Plate transport %1 positioning error</b>	<p>During the initialisation procedure or during the run. Plate transport can't reach the demanded position.</p> <p>Possible reasons for the error:</p> <ul style="list-style-type: none"> <li>• Inaccurate teaching. Especially, the teaching of the z position of the incubator drive and the "plate in" y position are critical for the loading and unloading of plate carriers.</li> <li>• Defective encoders.</li> <li>• Wrong belt tension misadjustment of the incubator slots</li> <li>• Insufficient lubrication</li> </ul>	<p><b>Recovery options:</b></p> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: System will try to repeat the last movement step.</li> <li>• <b>Ignore</b> button: Not advisable cause system cannot go on without sequence errors.</li> <li>• <b>Abort</b> button: Plate will be aborted.</li> </ul> <p><b>Troubleshooting:</b></p> <p>After error message occurs, make sure that there are no obstacles that jammed the plate transports movement.</p> <p>Push <b>Retry</b> button, if the error recurs, please call service to check the plate transport module.</p>
<b>Plate transport EEPROM error</b>	EEPROM error while reading / writing procedure.	Restart system again. If error recurs, please call service to change the instrument CU board.
<b>Please close the system cover</b>	During initialisation or when resuming from pause. System cover isn't closed.	<p>Close the system flap and push the <b>OK</b> button.</p> <p>If the error recurs after closing the flap, please call service to check the cover sensor.</p>
<b>Please configure the system in preparation for a standard WL. Ensure that the dilution tube rack is inserted.</b>	After adding plate and assay. Wrong predilution area is defined.	Push <b>OK</b> button. Make sure that correct predilution area is chosen for this assay and start work list again.

Error message:	Cause:	Action:
<b>Please remove the plate from the system</b>	During starting or stopping of a worklist. In order to save time in case OK is accidentally clicked before the plate is actually loaded, the software will not close the Load Plate dialog in case no opening and closing of the cover for loading a plate has been detected.	Open the system cover and (after approx. one second) close it again. Then, the dialog can be closed by pressing OK.
<b>Positioning error</b>	Motor error in scanner of reagent and sample rack. Scanner firmware does not work correctly. Electrical or mechanical problems of scanner.	If error occurs, please call service to check the bar code scanner of the loading bay.
<b>Rack scanner focusing error</b>	During a reading step of bar coded sample / reagent rack. The bar code scanner cannot be focused.	If error occurs please use the possibility to allocate the reagents and samples, manually. The bar code scanner has to be checked, please call service.
<b>Rack scanner motor error</b>	Motor error in scanner of reagent and sample rack. Scanner firmware does not work correctly. Electrical or mechanical problems of scanner.	If error occurs please use the possibility to allocate the reagents and samples, manually. The bar code scanner has to be checked, please call service.
<b>Rack scanner not detected</b>	During the initialisation procedure. Scanner of loading bay is not connected.	If error occurs please use the possibility to allocate the reagents and samples, manually. The bar code scanner has to be checked, please call service.
<b>Reagent ... is undefined</b>	After adding plate, assay and sample. A reagent has not been defined.	Open assay and add the missing reagent into reagent database. Restart the work list. <b>Note: the changes have to be saved, with the Save Button before they will get active.</b>
<b>Some required resources have not allocated to system positions</b>	After the loading dialogue. Not all required reagents have been allocated to a position.	Push OK button. Load all resources from the unallocated resources field into the appropriate position (reagents, samples, dilution tubes/plates, tips, buffers).
<b>Suspect tip pick up</b>	During tip pick up. The disposable tip adapter reached the Zmax position, the tip sensor detects a tip, but the pick-up force was not as high as expected.	This is a warning that is logged in the event log. No results are flagged. The software continues pipetting with the tip without user interaction. If the error recurs frequently, the teaching positions (mainly Zmax at the tip trays) and the disposable tip adapter have to be checked, please call service.

## Troubleshooting and Error Messages

### Error Messages

Error message:	Cause:	Action:
<b>System fluid low</b>	During the initialisation procedure or during the run.	Fill up the system liquid container with deionised water and push OK. If the error recurs after filling up the container, the level sensor has to be checked, please call service.
<b>System waste full. Empty the waste container.</b>	During initialisation procedure or during the run.	Empty the waste container and push OK button. If the error recurs after emptying the waste container the level sensor has to check, please call service.
<b>The disposable tips have been incorrectly loaded.</b>	During the tip type detection. Software detected a wrong type of tip.	After pushing the OK button the software displays to the loading dialogue where you have to check if the correct type of tips (300 µl or 1100 µl) are loaded to the correct position.
<b>There was an error found when printing the Document to LPT1: The device is not connected. Do you want to retry or cancel the job?</b>	After finishing a plate and getting a result.	<b>Recovery options:</b> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: Software will try to start the print job, again.</li> <li>• <b>Cancel</b> button: The print job will be cancelled.</li> </ul> Please check that the printer is switched ON and all cables are connected. Make sure that the right printer driver is installed. If the error recurs after checking the printer, please call service.
<b>Tip eject failure</b>	Error during the tip ejection in the tip eject station. The tip could not be ejected (the tip sensor still detects a tip although the pipettor performed a tip eject movement)	Remove tip manually from pipettor or trigger eject mechanism manually. Press the OK button after removing the tip manually. The system logs the failure in the event log and goes on with the next step. If the error recurs the disposable tip adapter and the teaching have to be checked, please call service.
<b>Unable to create text file ...</b>	Error during writing a file (network down or directory moved/deleted).	Check or change the target directory in the <b>Directories</b> tab of the <b>Options</b> dialog (see chapter 7.1.6 on page 7-8).
<b>Unknown colorimeter error code %1</b>	Unknown photometer error.	Restart system and software, if the error recurs, the whole photometer module has to be checked, please call service.
<b>Unknown command</b>	During initialization procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the concerning module.
<b>Unknown incubator error code %1</b>	Unknown incubator error.	Restart system and software, if the error recurs, the whole incubator module has to be checked, please call service.

Error message:	Cause:	Action:
<b>Unknown plate transport error code %1</b>	Unknown plate transport error.	Abort the work list, and restart software to initialize the plate transport. Restart the work list. If the error recurs the plate transport has to be checked, please call service.
<b>Unknown washer error code %1</b>	Unknown washer error.	Restart system and software, if the error recurs, the whole washer module has to be checked, please call service.
<b>Verification failed: %1</b>	During the photometer verification.	If the error occurs, change the lamp and check the filter configuration. Repeat the colorimeter verification test.  If the error recurs the photometer module has to be checked, please call service.
<b>Warning! Incubator tolerance of xx°C was exceeded.</b>	For elevated temperature incubation, if the incubation temperature monitored during the run does not correspond to the incubation temperature defined in the assay.	See chapter 9.3.2 on page 9-20
<b>Washer aspirate pump error</b>	During the initialization procedure or during a wash step. The poor vacuum quality is detected.	<b>Recovery options</b> during wash step: <ul style="list-style-type: none"> <li>• <b>Retry</b> button: Software will try to activate the aspirate pump again.</li> <li>• <b>Abort Plate</b> button: Plate will be aborted.</li> </ul> Before pushing the <b>Retry</b> button, please check that all tubes are connected correctly. Check that there are no kinks in the tubing. Check the bottle seals. Are the bottle lids closed correctly? If the error recurs, please call service to check the vacuum sensor and the washer aspiration pump.
<b>Washer aspirate pump drive failure</b>	During the initialization procedure or during a wash step. The aspirate pump is faulty.	<b>Recovery options:</b> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: Software tries to repeat the dispensing step.</li> <li>• <b>Abort Plate</b> button: The plate will be aborted.</li> </ul> Push the <b>Retry</b> button. If the error recurs, please call service to check the aspirate pump.
<b>Washer dispense pump drive failure</b>	During the initialization procedure or during a wash step. One of the wash buffer pumps is faulty.	<b>Recovery options:</b> <ul style="list-style-type: none"> <li>• <b>Retry</b> button: Software tries to repeat the dispensing step.</li> <li>• <b>Abort Plate</b> button: The plate will be aborted.</li> </ul> Push the <b>Retry</b> button. If the error recurs, please call service to check the wash buffer pumps.

## Troubleshooting and Error Messages

### Error Messages

Error message:	Cause:	Action:
<b>Washer EEPROM error</b>	EEPROM error while reading / writing procedure.	Restart the system again. If the error recurs the washer PCB has to be changed, please call service.
<b>Washer reagent level low</b>	After loading dialogue or during the run. One of the washing liquids is empty.	<b>Recovery options:</b> <ul style="list-style-type: none"><li>• <b>Retry</b> button: Software checks the level sensor again.</li><li>• <b>Abort</b> button: the work list will be aborted.</li><li>• <b>Ignore</b> button: the work list goes on without filling up the buffer.</li></ul> Refill the washer reagent and push the <b>Retry</b> button. If the error recurs after refilling, check the cables connections of level sensors or call service.
<b>Washer strip error</b>	Before wash step. One of the strips of micro plate isn't inserted correctly.	<ul style="list-style-type: none"><li>• <b>Retry</b> button: Strip check will be repeated.</li><li>• <b>Abort Plate</b> button: Plate will be aborted.</li></ul> After error occurs push the <b>Retry</b> button. The system will go on, if the error recurs abort the plate.
<b>Washer waste full</b>	During initialization procedure or during the run. Waste bottle is full.	<b>Recovery options:</b> <ul style="list-style-type: none"><li>• <b>Retry</b> button: System will check the level sensor again.</li><li>• <b>Abort Plate</b> button: Plate will be aborted.</li></ul> Empty washer waste bottle manually and push the <b>Retry</b> button. If the error recurs, the washer level sensor has to be checked, please call service.

Table 9-1: General Error Messages

## 9.2 Troubleshooting while Loading

This section describes the possibilities of troubleshooting in relation to the loading of samples, reagents, microtiter plates or other resources.

### 9.2.1 Troubleshooting while Loading Samples

#### 9.2.1.1 Unreadable Bar Codes

If the system has not been able to read one or several bar codes of samples:

1. Close the shown tabular Patient Editor dialog by clicking the Close button.
2. Remove the inserted rack.
3. Check the bar code labels on the tubes that the system failed to read. Make sure the labels are facing on the right-hand side and are not damaged or dirty. Make sure the bar code type is the same as on the tubes that were correctly read (otherwise, you may need to change your bar code settings, see chapter 7.2.5.2 on page 7-28).
4. Check the loading bay bar code scanner. If necessary, clean the glass pane (see chapter 8.3 on page 8-7).
5. Try to insert the rack again. The tabular Patient Editor dialog is displayed again.
6. If the system still fails to read these bar codes, remove the rack once more (**without** closing the tabular Patient Editor dialog).
7. Enter the unreadable Patient IDs manually.  
Do not remove or exchange any of the bar coded samples (the system compares successive readings).
8. Insert the rack again.
9. Assign the assays (see chapter 4.3.2 on page 4-6).




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*In the results, all manually entered samples will be flagged ("ManID" flag).*

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#### 9.2.1.2 Problems with reinserted Sample Rack

Each time you reinsert a sample rack on the same lane, the system compares the data read by the bar code scanner during two successive readings. If any difference is found between the first and the second reading, the system assumes that tampering may have occurred and:

- All Patient IDs entered manually in the tabular Patient Editor dialog between the first and second reading are deleted.
- Rack positions that returned discrepancies between the first and the second reading are signalled visually (see below) and the corresponding data is cleared.
- Rack positions for which the second reading is identical to the first are retained.

**Example:**

You insert a rack with 8 bar coded sample tubes for Patient IDs. The bar code scanner fails to read the bar code label on Position 6. When the tabular Patient Editor dialog is displayed, the first Patient ID is missing.

Patient IDs	
1.	Patient 07
2.	Patient 15
3.	Patient 14
4.	Patient 13
5.	Patient 12
6.	
7.	Patient 10
8.	Patient 05

Figure 9-1: Result of the first reading

You remove the rack, type in the missing Patient ID (e. g. "Patient 11") (or scan it with the hand-held scanner) and click on the Close button to close the tabular Patient Editor dialog.

Then you reinsert the rack on the same lane. When the tabular Patient Editor dialog is displayed again, if nothing else has changed, all 8 Patient IDs are listed in the Patient ID column.

Patient IDs	
1.	Patient 07
2.	Patient 15
3.	Patient 14
4.	Patient 13
5.	Patient 12
6.	Patient 11
7.	Patient 10
8.	Patient 05

Figure 9-2: Result of the second reading (no errors)

But, if you changed anything else on that rack, the manually entered ID(s) are deleted and any sample for which the bar code read in the second reading is not identical to the first bar code is corrected and marked. For example, if you inadvertently exchanged sample tubes "Patient 10" and "Patient 12" between the first and second readings, the tabular Patient Editor dialog displayed after the second reading looks like this:

Patient IDs	
1.	Patient 07
2.	Patient 15
3.	Patient 14
4.	Patient 13
5.	Patient 10
6.	
7.	Patient 12
8.	Patient 05

Figure 9-3: Result of the second reading (with errors)

You can see that the manually entered ID "Patient 11" has been deleted. Changed Patient IDs "Patient 10" and "Patient 12" have also been corrected and small boxes around position numbers 5 and 7 indicate that these positions have been changed between the first and the second readings.

#### To correct this:

1. Click on the Close button, remove the rack and insert it once more.
2. Enter the missing IDs manually without changing anything else.



3. Click on the **Close** button and reinsert the rack. All Patient IDs should now be displayed. You can assign assays to each sample as described below.

### 9.2.1.3 Racks tend to tip over Sideways

When inserting a sample rack onto a lane, make sure to keep your rack strictly level while pushing it in. If you push down on the end that you are holding, the other end may lift out of the lane and the rack may tip over. If this happens, please refer to the clean-up and decontamination procedures described in chapter 8.6 on page 8-11.

### 9.2.1.4 Using different Sizes of Sample Tubes

The standard T sample racks (see chapter 2.2.4.1 on page 2-13) usually accommodate tubes with a diameter between 9 and 16 mm and a height not to exceed 10 cm.

If you need to use smaller size tubes (e.g. Eppendorf tubes), narrower tubes or tubes with a specific shape, contact your service engineer to adapt and re-align your racks accordingly. The adapted racks will be identified by colored stickers and, in the **Load** dialog, these racks will be displayed in the corresponding color and identified by a different code letter (U, V, W, Y and Z).

The **Elisys Duo** system will not accommodate sample tubes that exceed 10 cm in height; therefore, these samples must be transferred into smaller tubes to be processed.

### 9.2.1.5 There is not enough Space to fit all the Sample Tubes

Each rack can accommodate 16 tubes. The sample and reagent unit includes 12 rack tracks, some of which are reserved for the reagents. Therefore, the maximum number of sample tubes that you may load at the beginning of a run is:

- 144 tubes (9 racks) if you intend to process one or two assays;
- 96 tubes (6 racks) if you intend to process more than two assays.

The continuous loading system may allow you to insert new samples at a later stage. The continuous loading system is explained in chapter 5.6 on page 5-44

### 9.2.1.6 Sample Tubes with unknown Bar Code Label Types

See chapter 7.2.5.2 on page 7-28 on how to set the scanner parameters and determine the type of bar code used.

### 9.2.1.7 The System has not been able to read some of the Sample Bar Codes

Either the problem is also a problem of bar code settings (i.e. the bar code scanner has not been set to read the type of bar code that is actually used on the tubes), then the answer is the same as in chapter 9.2.1.6 above, or the setting are correct but the scanning fails for another reason (e.g. the bar code printing is fuzzy); in this case, see chapter 4.3.2 on page 4-6

### 9.2.1.8 The System always requires that the loading Process be carried out from right to left

Under standard scanner settings, loading will always be directed from right to left, i.e. the LED to the very right will light up.

The standard direction can be changed in the **System Setup**, under the **Sample Rack** tab in the field **Auto Load** (see chapter 7.2.5 on page 7-25).

#### 9.2.1.9 You want to process two Tubes of each Sample (Duplicate Sample Tubes)

You are not allowed to load sample tubes with identical bar codes. If you do, an error message is displayed:

Duplicate patient ID .....

Edit the patient IDs so that only one tube is used per patient.

If you really want to process two tubes of each sample, you have to use different bar code labels for each tube.

What the system does allow you to do is to test the same sample twice with the same assay on the same plate (replicate wells), by using the multiple determination option of the **Add Patient** dialog (see chapter 5.2.1 on page 5-7)). In that case, the sample will be pipetted twice out of the same tube and dispensed into two consecutive wells of the same plate.

### 9.2.2 Troubleshooting while Loading Reagents

#### 9.2.2.1 Non-Bar coded unstable Reagents

If the unstable reagent you loaded is not bar coded (or has an incorrect bar code), an error message is displayed:

"Error! Barcode "..." is not correct for reagent "(reagent name)".

You can click on the **OK** button to close the message but it will appear again and again until the end of the preset preparation time. When the preparation time is over, the system assumes that you have not loaded the required unstable reagent and that you need to abort the plate for which this reagent was required. It therefore opens the **System Paused** dialog (see chapter 4.8.5 on page 4-55) to allow you to abort this plate.

At this stage, if you had actually loaded the required unstable reagent, **DO NOT** abort any plates and just click on the **Resume** button. The run continues normally (the system actually dispenses the unstable reagent) but in the log file, a warning is included stating that the reagent was not loaded on time and the volume of the unstable reagent is not checked. This procedure is therefore not satisfactory. This is why it is recommended to always use bar coded unstable reagents.

#### 9.2.2.2 Unreadable Bar Codes

If the system has not been able to read one or several bar codes of reagents:

1. Remove the inserted rack.
2. Check the bar code labels on the tubes/bottles that the system failed to read. Make sure the labels are facing on the right-hand side and are not damaged or dirty. Make sure the bar code type is the same as on the tubes/bottles that were correctly read (otherwise, you may need to change your bar code settings, (see chapter 7.2.5.2 on page 7-28)).
3. Check the loading bay bar code scanner. If necessary, clean the glass pane (see chapter 8.3 on page 8-7).
4. Try to insert the rack again.
5. If the system still fails to read these bar codes, assign the reagents manually in the **Load** window.

## 9.3 Worklist Troubleshooting

### 9.3.1 Error Detection while creating Worklist

If, while conducting its verification process (after you click on the OK button in the Lot Specific Value dialog), the system does not identify any problem, the Worklist window will be displayed and the status of the plates in the Worklist Parameters will be **Not loaded** (see chapter 4.6.1 on page 4-16).

Conversely, if the system detects a problem, a corresponding error message will be displayed.

If the error is related to the way you defined your worklist (e.g. if you tried to combine too many assays and patients and the system cannot find a way to schedule them adequately), correcting the source of the error will involve going back to the Setup Panel dialog. To do this:

1. Click on the OK button in the error message box. The Worklist window appears but Error is displayed (instead of **Not loaded**) as the status for that plate. If the status for a plate appears as Error, the respective plate cannot be processed.
2. Click on the Lot Specific Values button in the Worklist window to re-open the Lot Specific Values dialog.
3. Carry out the necessary changes and click on the OK button again. If you have successfully corrected the problem, the Worklist window will be displayed again but this time the status for this plate in the Worklist Parameters is **Not loaded**.



If the error is related to the assay file you are using (e.g. if the reading parameters refer to a photometer filter not available on the instrument or if one of the reagents required for the assay has not been entered in the reagent database (see "Assay Programming Manual"), open your assay file and check it thoroughly (edit it if necessary). If you use only validated assays for **Elisys Duo**, you should not encounter this kind of problem.

If the error is related to a problem in the system itself, please refer to the error message list (see chapter 9.1 on page 9-1).

### 9.3.2 Monitoring of the Incubation Temperature

For elevated temperature incubation, if the incubation temperature monitored during the run does not correspond to the incubation temperature defined in the assay:

- A general warning will be included in the **Title Block** section of the **Result Report** ("Warning! Incubator tolerance of xx°C was exceeded." (see chapter 4.9.1.1 on page 4-60).
- In the **Combined Report**, all affected samples will be flagged (IncKo - Incubation overrun, see chapter 4.9.1.10 on page 4-61 and chapter 4.9.2.1 on page 4-62) and the results for these samples will not be calculated.

Example:

If the temperature defined in the assay is 37°C +/- 1°C, there is a flag and no result calculation when:

- the mean incubation temperature is < 36°C or > 38°C or
- the maximum incubation temperature is > 38°C.

If the temperature defined in the assay is 37°C +/- 1°C, there is no flag and the results are calculated when:

- the minimum incubation temperature is < 36°C and
- the mean incubation temperature is > 36°C and < 38°C.

Temperature (°C)			
Min.	Mean	Max.	
36.3	37	37.5	No Flag, Result calculated
35.5	36.5	37.5	No Flag, Result calculated
36.3	37.5	38.2	Flagged, Result not calculated
34.3	35.8	37.5	Flagged, Result not calculated

The same warning and flags apply if there is a discrepancy between the actual duration of an incubation step during a run and the incubation duration defined in the assay. Incubation duration errors apply both to room-temperature and elevated-temperature incubations.

Using the **Outliers** dialog, it is possible to calculate results for samples invalidated because of incubation errors (see "Instructions for use Manual"). This, however, should only be done for reference purposes and under the laboratory supervisor's sole responsibility.

# 10 Installation or Removal of the System

## 10.1 Installation of the System



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*Please note that the **Elisys Duo** system may only be installed by authorized service personnel. For the installation, the currently valid version of the chapter "Installation" of the Service Manual must be used.*

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*See chapter "Technical Data" (see chapter 11 on page 11-1) for power requirements, computer and connections, installation dimensions, weight, and environmental conditions.*

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*After the installation, the user of the **Elisys Duo** system receives an installation qualification which documents the proper installation of the **Elisys Duo** system.*

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## 10.2 Removal of the System



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*The removal of the **Elisys Duo** system must be performed by authorized service personnel.*

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*If the **Elisys Duo** system moves within the plant, the authorized service personnel must perform a complete reinstallation. If this reinstallation is omitted, this can cause damage of the system or irregular pipetting performance!*

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# 11 Technical Data

## 11.1 Power Requirements

Voltage:	100 V - 240 V +/- 10 %
Amperage:	3.2 A - 1.3 A
Frequency:	50 - 60 Hz
Power consumption:	max. 320 VA
Fuses:	primary 3.2 AT

## 11.2 Laser of the Bar Code Scanner

Class:	Class 2 laser product Class II laser product
Maximal output radiation:	1.3 mW
Pulse duration:	70 $\mu$ s
Emitted wave length:	650 - 690 nm
Standards:	EN 60825-1: 2003-10 Complies with 21 CFR 1040.10

## 11.3 Integrated Computer and Connections

**Hardware:**

Processor:	Pentium Celeron M
Memory (RAM):	512 MB
Hard disk:	40 GB
Ports:	<ul style="list-style-type: none"><li>• 3 USB ports</li><li>• 1 external monitor connector</li><li>• 1 serial RS 232 ports</li><li>• 1 external mouse/keyboard connector</li><li>• 1 10/100Base-TX Fast Ethernet (LAN)</li></ul>
Integrated monitor:	15 inch Touch screen

**Software:**

Operating system	Microsoft® Windows® XP (UK English) with Service Pack 2 or newer
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## 11.4 Installation Dimensions and Weight

Width:	125 cm (49.2 inch)
Dept:	90 cm (35.4 inch)
Height:	115 cm (45.3 inch)
Weight:	100 kg (220.5 lb) without accessories



## 11.5 Environmental Conditions

Environmental Condition:	This standard applies to equipment designed to be safe at least under following conditions: Indoor use.
Temperature:	Operating: 15 to 30 °C (59 to 86 °F) Storage: 5 to 50 °C (41 to 122°F) Transport: 5 to 50 °C (41 to 122°F)
Humidity:	Operating: 30 - 80 % non-condensing Storage: 10 - 85 % non-condensing Transport: 10 - 85 % non-condensing
Pollution degree:	2
Installation Class:	2
Sunlight:	No direct sunlight May mislead optical sensors and affect performance
Altitude	Up to 2000 m (6561 ft.) above mean sea level Storage: as required for air travel
Dust:	No excessive dust

## 11.6 Noise

70 dB A (distance 1 m (39.37 inch))

## 11.7 Packaging

Dimensions (WxDxH):	125 cm x 90 cm x 115 cm (49.2 inch x 35.4 inch x 45.3 inch)
Weight:	143 kg (315.3 lb)



## 12 Appendix

### 12.1 Accessories and Consumables (Ordering Information)

See separate accessories and consumables list.

## Appendix

### Accessories and Consumables (Ordering Information)

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**Do**

- Always wear proper personal protective equipment: lab coat and gloves (plus eye protection when performing maintenance tasks).
- Always turn off the instrument before cleaning.
- If liquid gets inside the instrument, immediately disconnect the power cord and clean the affected areas as described in the Instruction for use Manual.
- Always dispose of waste and used consumables in compliance with your laboratory guidelines and federal, state and local regulations.
- Check system liquid and liquid waste container before a run.

**Do Not**

- Do not interfere with the processing unless absolutely necessary. If you need to do so, pause the system first.
- Do not use any disinfectant containing alcohol for perspex surfaces (e.g. instrument cover) or for the manifold.
- Do not bring disinfectant into contact with bearings and guides (lubricant may dissolve).
- Do not use disinfectant in the vicinity of circuit boards and light barriers.
- Do not clean heated incubators.
- Do not refrigerate reagent racks.



<b>Elisys Duo</b>	<b>Maintenance Daily and Weekly Checklist</b>	<b>Laboratory: Instrument No:</b>	<b>Week No: Month / Year:</b>
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<b>Daily Maintenance Procedure</b>		<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>	<b>Saturday</b>	<b>Sunday</b>
<b>Start Up</b>	Check system liquid and waste liquid containers							
	Check pipettor tubing and syringe for air bubbles or leakages							
<b>After each run</b>	Inspect instrument deck, plates, racks, etc. for spillages							
	Remove reagent and sample racks							
	Remove used test and dilution plates							
	Check the waste bag							
	Check system liquid and waste liquid containers							
<b>Shut Down</b>	Inspect instrument deck, plates, racks, etc. for spillages							
	Remove reagent and sample racks							
	Close the finished worklist(s) and files							
	Exit the user software and shut down windows							
	Switch off the instrument							
	Check the waste bag							
	Ceck system liquid and waste liquid containers							
	Remove all disposable tip racks							
	Remove all reagent and control bottles from the racks or instrument and store them							
	Clean or decontaminate the instrument (if necessary)							

<b>Weekly Maintenance Procedure</b>	<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>	<b>Saturday</b>	<b>Sunday</b>
Run a assay to clean/decontaminate the washer							
Perform the shut down steps of the daily maintainance							
Clean and decontaminate the instrument							

Operator/Supervisor: .....

<b>Elisys Duo</b>	<b>Maintenance Monthly Checklist and Specials</b>	<b>Laboratory: Instrument No:</b>	<b>Year:</b>
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<b>Monthly Maintenance</b>	<b>January</b>	<b>February</b>	<b>March</b>	<b>April</b>	<b>May</b>	<b>June</b>	<b>July</b>	<b>August</b>	<b>September</b>	<b>October</b>	<b>November</b>	<b>December</b>
Perform the weekly maintenance												
Clean and decontaminate the system liquid and waste liquid containers												
Clean and decontaminate the wash buffer bottles (bottles only)												
Clean the head of the pipettor												
Clean the room-temperature incubators												
Perform a backup												
Check the performance of the pipettor												

<b>Special procedures</b>	<b>Date</b>	<b>Operator</b>	<b>Comments</b> (circumstances, parts affected, details...)
Heavy liquid overflow clean-up			
Pipettor decontamination			
Washer manifold needles (clean needles)			
Vacuum and trap flask maintenance			
Photometer (bulb replacement, filter maintenance or replacement)			
Fuse replacement			
Other			

Operator/Supervisor: .....



(To be completed by your service engineer or your local technical support person.)

**Contact Information:**


**Instrument Serial Number:**

--

**Maintenance and Servicing Visits:**

Date	Description	Done by

Date	Description	Done by

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